

## UNITED STATES DISTRICT COURT

## DISTRICT OF MINNESOTA

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In Re: Bair Hugger Forced Air ) File No. 15-MD-2666  
Warming Devices Products ) (JNE/FLN)  
Liability Litigation )  
October 26, 2017  
Minneapolis, Minnesota  
Courtroom 12W  
9:39 a.m.  
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BEFORE THE HONORABLE JOAN N. ERICKSEN  
UNITED STATES DISTRICT COURT JUDGE

THE HONORABLE FRANKLIN L. NOEL  
UNITED STATES MAGISTRATE JUDGE

THE HONORABLE WILLIAM H. LEARY  
RAMSEY COUNTY DISTRICT COURT JUDGE

**(MOTIONS HEARING - VOLUME III)**APPEARANCES

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## P R O C E E D I N G S

(9:39 a.m.)

THE COURT: Good morning. Welcome back. Please be seated. All right. Still no Mr. Gordon, but you left him a chair in case, right, in case he feels better? What's his situation today?

MAGISTRATE JUDGE NOEL: How is he?

MS. CONLIN: He is still suffering from a migraine, Your Honors.

THE COURT: And did it spread to Mr. Ciresi? Is it me?

MS. CONLIN: No, he had a long-standing conflict. He's going to be showing up in a few minutes, Your Honor.

THE COURT: Okay. Everyone over here is feeling all right. Did you want to start by asking?

MAGISTRATE JUDGE NOEL: Yes. Mr. Gordon, Corey Gordon, could I ask you, so yesterday you had your fishless lake analogy, and I was somewhat confused by it. And I asked a question, and you referred me to the nine studies, and I'm assuming the nine studies you were referring to are the nine that was in one of the slides that I think was used by Mr. Blackwell.

MR. GORDON: Yes, Your Honor. Mr. Blackwell used it. Also, Mr. Goss used it.

THE COURT: Who used it isn't the main part.

1 MAGISTRATE JUDGE NOEL: And it's the one that  
2 lists Hall through Oguz.

3 MR. GORDON: That's correct.

4 MAGISTRATE JUDGE NOEL: And it was my  
5 understanding that what those studies show is that there is  
6 no increased rate of infection when they studied the Bair  
7 Hugger, but that it's not and that none of these are  
8 double-blind gold standard clinical studies that show no  
9 bacteria coming out of the Bair Hugger. Am I wrong about  
10 that?

11 MR. GORDON: Slightly. Actually, yes. All of  
12 these nine studies were not specifically infection studies.  
13 There are three or four of them where infection was noted  
14 where there were real procedures done, and I should say in  
15 none of them were any infections noted, but they weren't  
16 primarily infection studies. They were looking at various  
17 issues surrounding the notion of does the Bair Hugger cause  
18 an increase in bacteria either in the air, surgical site  
19 coming out of the Bair Hugger.

20 One of them, for example, introduced a test  
21 bacteria at the intake of the Bair Hugger and then measured  
22 with agar plates coming out so that they knew if bacteria  
23 were going in. They found that no bacteria were coming out.  
24 That was one method of study.

25 Another was -- my favorite study was where they

1        somehow recruited a handful of, I think eight University of  
2        Minnesota students who were willing to lay for four hours on  
3        an operating table.

4                THE COURT:    For money, I'm sure.

5                MR. GORDON:    I'm sorry?

6                THE COURT:    For money.

7                MAGISTRATE JUDGE NOEL:    They got paid to do this.

8                MR. GORDON:    I assume that they were paid.

9                MAGISTRATE JUDGE NOEL:    At least the pizza and  
10       beer.

11               MR. GORDON:    I would hope so.

12               THE COURT:    I had an University of Minnesota  
13       student on a jury, and he said afterwards he was so sorry  
14       that the trial wasn't longer because he needed the 40 bucks  
15       a day.

16               MR. GORDON:    But a couple of them were in fact  
17       randomized trials.    You can't really do a blinded trial with  
18       warming versus something else.    And the most recent one, and  
19       probably the most compelling one, was the Oguz study, which  
20       was a randomized trial, over 80 subjects, 40 of them were  
21       randomized to Bair Hugger, the other 40 had orthopedic  
22       procedures done using the HotDog.    And they were measuring  
23       bacterial contamination with sedentation weights, agar  
24       plates in six different locations.    They were specifically  
25       looking to see is the method of warming, does that have any

1 impact on bacterial contamination?

2 They were also looking at other potential factors  
3 such as whether the so-called laminar flow was on or not,  
4 the number of personnel in the room during surgery, and  
5 there was a fourth factor. The only one that they found  
6 that did actually have a statistically significant impact on  
7 the amount of bacteria that they collected was whether the  
8 laminar system was on or not. If it was on, the rates were  
9 significantly lower than if when it was off.

10 When they compared Bair Hugger to HotDog  
11 throughout the procedure, and these were short orthopedic  
12 surgeries, short being defined as less than an hour,  
13 although, I think one or two of them were in fact hip  
14 arthroplasties apparently done within hour. And in the case  
15 of the warming device, there was no difference, no  
16 statistically significant difference. In fact, that was --  
17 that was kind of really what they were looking for.

18 MAGISTRATE JUDGE NOEL: Okay. But I guess the  
19 reason I -- my confusion is I was under the impression that  
20 there's wildly disparate interpretations of these studies  
21 because some of them show up on the plaintiffs' slides,  
22 correct? In other words, Tumia and Moretti and Zink I  
23 thought were all studies that plaintiffs cite when we ask  
24 them about bacteria.

25 MR. GORDON: I think that's true, Your Honor.

1 And this is, I would submit that this is lawyer  
2 interpretation and lawyer science. Obviously, I'm doing a  
3 lot of interpreting too, but these nine studies have been  
4 uniformly, uniformly interpreted by the medical community  
5 and the scientific community as standing for the proposition  
6 that there's --

7 MAGISTRATE JUDGE NOEL: That there are no fish in  
8 that lake.

9 MR. GORDON: I have to say, Your Honor, I've  
10 gotten a great deal of critique on that analogy, and I wish  
11 I could strike it from the record. If I were a Congressman,  
12 I'd have it removed from the record and make believe it  
13 never happened. It was a dreadfully --

14 THE COURT: Give a man a fish, not happening.

15 MR. GORDON: Poor fish analogy.

16 MAGISTRATE JUDGE NOEL: Thank you for your answer.  
17 It explains or at least clarifies my confusion.

18 MR. GORDON: Thank you, Your Honor.

19 MAGISTRATE JUDGE NOEL: Did you want to say  
20 something, Ms. Zimmerman?

21 MS. ZIMMERMAN: Would Your Honors like to hear  
22 from the plaintiffs on this?

23 MAGISTRATE JUDGE NOEL: Sure.

24 MS. ZIMMERMAN: Just very briefly, I think that  
25 Mr. Gordon summed it up perfectly in his answer to Your

1 Honor's question. This is lawyer argument and  
2 interpretation of studies and that goes to the weight. It's  
3 not to the admissibility. We can talk about the different  
4 studies, but I'll leave it at that at this point.

5 MAGISTRATE JUDGE NOEL: To follow up the analogy,  
6 you think there are fish in that lake.

7 MS. ZIMMERMAN: I do think there are fish in the  
8 lake, Your Honor.

9 THE COURT: All right. Before we move on to the  
10 scheduled argument for today, which is the summary judgment,  
11 we have some experts still either to discuss or to agree  
12 that they won't be discussed. And let's first find out  
13 about plaintiffs' motion. I don't know really who to talk  
14 to here, but Settles, Keen and Kuhn.

15 MR. ASSAAD: Your Honor, we're happy to rest on  
16 the papers for Kuhn, Professor Kuhn and Dr. Settles.

17 THE COURT: And what about Keen?

18 MR. ASSAAD: And Keen as well.

19 MR. BLACKWELL: For once in agreement, Your Honor,  
20 us as well, the defense too.

21 THE COURT: I thought so, but I just thought I'd  
22 make a check.

23 Okay. So that leaves David and Ulatowski, and I  
24 know that David has not only engineering but also regulatory  
25 testimony. Ulatowski is regulatory only. Do you want to



1 dispense with Ulatowski now? Or do you want to separately  
2 argue about Ulatowski?

3 MR. BANKSTON: I believe so, Your Honor. I think  
4 that in fact it may shorten the argument on David if we talk  
5 about Ulatowski first.

6 THE COURT: All right.

7 MR. BANKSTON: And in effect, we could do it all  
8 in one big ball of wax. Ulatowski, move to David, you know,  
9 it's a matter of how you want to handle it.

10 THE COURT: Well, except that one is your motion.  
11 Well, I guess it isn't really.

12 MR. WINEBRENNER: Your Honor, we're happy to  
13 address --

14 THE COURT: Wait a second. Wait a second, who are  
15 you? Sorry.

16 MR. WINEBRENNER: I'm Joe Winebrenner for the  
17 defendant, and I prepared some remarks on Dr. David's motion  
18 to exclude. And I actually intended to rest on the papers  
19 with regard to the regulatory piece deferring the common  
20 ground to Ms. Ahmann, who is going to comment on  
21 Mr. Ulatowski.

22 THE COURT: All right.

23 MR. WINEBRENNER: We can take him up in either  
24 order, whichever the Court prefers.

25 THE COURT: All right. You, Mr. Bankston, I'd

1       like to hear from you.

2               MR. BANKSTON: Yes, Your Honor. I'm going to try  
3       to keep things moving. My credo has always been power  
4       corrupts and PowerPoint corrupts absolutely. I'm going to  
5       keep things moving today.

6               THE COURT: I'm with you except for the first part  
7       of that. That ain't right.

8               MR. BANKSTON: Mr. Ulatowski is a long time FDA  
9       employee, was involved for his entire career in the  
10      evaluation, regulation and compliance enforcement of medical  
11      devices. He was in the Center For Devices and Radiological  
12      Health. The type of organization, the part of the  
13      organization that deals specifically with the medical  
14      devices as opposed to the pharmacology and all the other  
15      stuff that the FDA does.

16              Mr. Ulatowski has decades of experience with the  
17      FDA. He's been offered to talk about regulatory issues and  
18      most fundamentally is the idea that compliance with the  
19      510(k) regime and the minimum federal regulations  
20      surrounding the 510(k) regime, in other words, the  
21      continuing regulatory duties that Bair compliance with that  
22      is relevant in some way to plaintiffs' design defect and  
23      failure to warn claims and negligence claims in this case.

24              In other words, I believe it is Mr. Ulatowski's  
25      position, this was a little unclear at deposition, that he

1 is not arguing that 510(k) compliance equals nonnegligent  
2 design, but instead is arguing something more like 510(k)  
3 compliance is somehow at least relevant to the issue of  
4 standard of care and, therefore, wants to talk about all the  
5 510(k) compliance issues.

6 So, first, to take up as a threshold legal matter,  
7 we've devoted some time in the brief to talking about why we  
8 believe Mr. Ulatowski's testimony is generally prejudicial  
9 and confusing and a waste of time under 403. We cited a lot  
10 of authority from recent years in the MDL context talking  
11 about why the introduction of testimony about Bair  
12 compliance and diving into the really the labyrinthian  
13 regulations that surround these products is not a good use  
14 of the Court's time and is a definite threat of jury  
15 prejudice and absolute confusion over what the federal  
16 clearances mean versus federal approvals versus what all of  
17 these things end up meaning in terms of what the jury is  
18 actually supposed to decide.

19 I think the best recent discussion in this is last  
20 year, the Fourth Circuit in a case called *CR Bard*. This was  
21 the pelvic repair MDL. And this is a very extensive  
22 discussion of really the kinds of problems posed when the  
23 FDA testimony looks a lot like what it does in this case  
24 where you have two experts who are going to argue about not  
25 only whether the product complied with regulations as a Bair

1 factual matter, but also the over-arching import of those  
2 regulations what they actually mean, what they're able to  
3 actually guarantee the public. And when you have these two  
4 experts engaged in this kind of battle, you end up having,  
5 you know, a huge amount of the trial and expenditure devoted  
6 to something that is not actually in the jury's  
7 consideration.

8 Ultimately, what the FDA does and what the 510(k)  
9 process does has marginal, if any, relevance at all to  
10 whether this product is unreasonably dangerous. Answering  
11 the question of what the FDA does doesn't really help you  
12 answer that question.

13 JUDGE LEARY: Let me ask you this, when you  
14 question the judgment of the FDA, why is their process for  
15 approval not relevant?

16 MR. BANKSTON: Well, I think you need to  
17 understand the difference between FDA approval, which you've  
18 referenced which this product does not have, and the  
19 difference between pre-market clearance.

20 JUDGE LEARY: Let's be more precise. Let's talk  
21 about the FDA letter, 2017 letter.

22 MR. BANKSTON: Okay.

23 JUDGE LEARY: If the plaintiffs are going to  
24 question the judgment of the FDA in terms of the quality and  
25 quantity of information they had when they issued that

1 letter, why is it not relevant to talk about what the FDA  
2 does as part of a regulatory process?

3 MR. BANKSTON: Sure. Let me do two parts of that.  
4 First of all, we absolutely question the judgment behind  
5 that 2017 letter. We question the process by which it's  
6 created. And if that does have to become --

7 JUDGE LEARY: I understand it. Let's get to the  
8 second part.

9 MR. BANKSTON: Okay. Well, the important part  
10 about that 2017 letter is if that ever comes into any part  
11 of this court and this trial, we're going to have to go down  
12 a side road about the author of that letter, and some very  
13 disturbing criminal acts that call into question his basic  
14 integrity not only as a human being but as a regulator. And  
15 we don't think that that's a good use of this Court's time.

16 THE COURT: Not by "person." It comes out as an  
17 agency letter.

18 MR. BANKSTON: Sure.

19 THE COURT: So you're going to rip apart some  
20 fellow. I'm assuming it's a man working for the FDA?

21 MR. BANKSTON: Correct. One of the, the head  
22 scientific advisor of the FDA. And, yes, there's absolutely  
23 no way to avoid introducing the crimes of moral turpitude  
24 that are very much on the record, and this is some very  
25 disturbing stuff.

1 JUDGE LEARY: Well, let's just slow down a little  
2 bit. The FDA letter is, I would assume, based on what the  
3 FDA undertook from the beginning of Bair Hugger up until the  
4 time that the letter was issued. So it seems to me that  
5 there's relevance not only in terms of explaining what the  
6 FDA does in writing that letter, but also there's relevance  
7 in explaining what the FDA did up until the point of that  
8 letter from the beginning of Bair Hugger up until the time  
9 of that letter. It seems to me to be all relevant.

10 MR. BANKSTON: I don't share your assumptions  
11 about the nature of that letter, but I do think let's go  
12 ahead to the second part which draws into everything that  
13 happened before that letter and whether or not that is  
14 relevant. And we have to ask ourselves what did the FDA do?  
15 And that's extensively discussed in the cases we've decided  
16 of what the FDA did during this 510(k) process.

17 So as a beginning threshold matter, we believe  
18 that this Court is bound by the U.S. Supreme Court in  
19 *Riegel*, in *Medtronic*, saying that the 510(k) process does  
20 not speak to safety and effectiveness.

21 JUDGE LEARY: So what value ultimately is it for  
22 the FDA to embark on a process in which they at one level or  
23 another pass judgment over a product such as Bair Hugger?  
24 Is that totally an unnecessary exercise irrelevant to the  
25 public, irrelevant to marketing?

1 MR. BANKSTON: No, I believe that the 510(k)  
2 process has a purpose, and it's purpose is not safety and  
3 effectiveness.

4 JUDGE LEARY: And tell me about that purpose.

5 MR. BANKSTON: The 510(k) purpose is to remove  
6 products that do not have safety questions from that  
7 consideration by determining if they are substantially  
8 equivalent to an already legally marketed product that has  
9 been found to be safe and effective.

10 JUDGE LEARY: In the FDA's judgment, that was Bair  
11 Hugger.

12 MR. BANKSTON: Correct. So to start with the  
13 first threshold part is what did the FDA do and does it have  
14 any value? We definitely have legal arguments about that.  
15 Moving on specifically to what did the FDA do specifically  
16 with this specific product? We also have some very  
17 important arguments about that as well.

18 So but just as an introductory threshold matter,  
19 we believe if you look at the case law, many, many courts in  
20 this exact MDL context said we are controlled by *Riegel*, we  
21 are controlled by *Medtronic*. If we are to find that the  
22 510(k) process has any relevance to safety and  
23 effectiveness, if that's what that process is designed to  
24 do, we are in direct contact with Supreme Court authority.

25 So on a legal matter, we think immediately it goes

1 out. Ulatowski has been excluded on this exact basis  
2 numerous occasions, and those cases are discussed in the  
3 *Next Gen* litigation, in the *Ethicon* litigation. These  
4 matters are extensively discussed on those terms, and that's  
5 in a vacuum of purely theoretically what the 510(k) process  
6 does. That's totally separate and aside from the  
7 fundamental reliability issues that Ulatowski has in this  
8 case regarding what specifically happened with this product.  
9 And maybe it's better if I move on a little bit to that.

10 The law is there and can be read. What I think I  
11 need to bring everybody up to speed on is the factual record  
12 of what happened in this product. Mr. Ulatowski testified  
13 that he was going to, you know, he's going to come to  
14 opinions about how the FDA reached a safety decision or  
15 endorse this product on a safety level and did so through  
16 the 510(k) process.

17 Now, one of the obvious big questions in this case  
18 we have a product that was first 510(k)'d for nonoperating  
19 room use with a substantial equivalent product that was also  
20 a nonoperating room use product. When the I guess what you  
21 call the middle iteration of the Bair Hugger, the Bair  
22 Hugger model 500 was the first product that was going to be  
23 introduced into the operating room for use. That was  
24 subject to a 510(k) process.

25 We talked to Mr. Ulatowski about that process, and



1 he told us, well, you know, one of the challenges in this  
2 case is the decision making documentation for that 510(k)  
3 decision is not available. It was not available for my  
4 review, so I have to speculate about what the FDA did during  
5 that process.

6 During that process, the FDA has to follow a flow  
7 chart to ask questions. If you answer certain questions  
8 "yes," you move on to the next question. If you answer  
9 "no," it directs you to a different part. It's a basic kind  
10 of flow chart. Where are the elements of this flow chart,  
11 if the FDA asked itself this product, does it have the same  
12 indications statement, the same indications for use as the  
13 prior product?

14 If the answer to that question is "yes," the FDA  
15 is done. You don't have to ask any questions about safety.  
16 You've now cleared the product because it has the same  
17 indication for use. There's no changes in the indication  
18 for use, so there can be no safety issues by that change.

19 If the FDA finds that, yes, the indications for  
20 use have changed, now there must be some sort of inquiry by  
21 a reviewer. Do those new changes raise new questions of  
22 safety? And then that's the process that they're supposed  
23 to follow.

24 When asking Mr. Ulatowski, so how does this play  
25 out with respect to the Bair Hugger? Mr. Ulatowski says the

1 FDA would find that the change from outside of an operating  
2 room to use of an inside of a delicate operating procedure  
3 would be a change in indications for use or indication  
4 statement. Therefore, the reviewer would answer that "yes",  
5 and would then next ask does that change alter any of your  
6 safety questions?

7 The problem with that analysis is that we actually  
8 do have the 510(k) decision making documents. Apparently,  
9 they were provided to Mr. Ulatowski in the prior *Walton*  
10 litigation, not part of his report in this matter, and he  
11 certainly wasn't aware that they existed. Those documents  
12 show that there was a serious error made in this 510(k)  
13 review process.

14 As we put screen shots all throughout our motion,  
15 we have the actual flow charts, the actual reviewer comments  
16 and the entire process that he followed. And when he got to  
17 the question does the Bair Hugger 500 have the same  
18 indication statement as the Bair Hugger 200? He said yes.  
19 So then his next question, which is does it raise new  
20 questions of safety? He doesn't have to answer that  
21 question. And when they have the narrative part saying what  
22 did the FDA do to determine new issues of safety and  
23 effectiveness? He writes "N/A" because he does not have to  
24 answer that question if that's the finding he made. We  
25 believe that's a clearly erroneous finding. It's very

1       problematic.

2               Mr. Ulatowski says, well, maybe the FDA didn't  
3       find a change to OR use to be significant. Speculating on  
4       that. And I would submit that if so, if the FDA found that  
5       the change from outside an OR to the use of an ultra clean  
6       orthopedic surgery wasn't significant then I would submit  
7       that the FDA is broken and needs to be fixed because that is  
8       an absolutely dangerous conclusion to make. I mean if you  
9       have me on the record in front of a federal court right now,  
10      I will tell you without qualification the FDA is broken and  
11      needs to be fixed.

12             But in this specific case, we have documentary  
13      evidence showing that the very thing that we're going to try  
14      to use the 510(k) to establish safety and effectiveness of  
15      the product was not answered by the 510 reviewer and that  
16      the FDA has never during the 510(k) process meaningfully  
17      reviewed the movement of the Bair Hugger from outside an OR  
18      into an OR. Mr. Ulatowski cannot give reliable opinions on  
19      this entire subject matter and that is extremely problematic  
20      to us. And this is really not a matter that we would need  
21      to pull out and discuss in front of the entire jury.

22             Obviously, 403, one of the questions is is it  
23      going to make this a mini-trial? There is going to be  
24      nothing mini about this part of the trial. If we have to go  
25      into this, there's going to be, as you've seen from our

1       punitive damage motion, as you've seen from other briefing,  
2       there are so many disputed issues about what went on with  
3       the FDA in this case. For example --

4               THE COURT: Let me just ask you, I am curious  
5       about your understanding of the application of the hearsay  
6       rule covering public records:

7               803.8, "A record or statement of a public office  
8       is non-hearsay if it sets out a matter observed while under  
9       a legal duty to report, but not including, in a criminal  
10      case, a matter observed by law enforcement," of course.

11              And then I think what you're talking about with  
12      your, and I'm curious what this moral turpitude, et cetera,  
13      is of course. I suppose that would go to you're talking  
14      about something under 803.8(B): "The opponent does not show  
15      that the source of information or other circumstances  
16      indicate a lack of trustworthiness." But that is an  
17      admissibility question. It's not a jury question.

18              MR. BANKSTON: Correct.

19              THE COURT: So I'm curious about how you're -- I  
20      mean you seem so exercised about the fact that there would  
21      be a mini-trial, but I'm wondering how you square that with  
22      the Rules of Evidence that would apply?

23              MR. BANKSTON: I agree with you in respect that  
24      there is several categories of documents that would likely  
25      never be admissible under any scenario. That is not to say

1       that having Mr. Ulatowski and Dr. David slug it out for days  
2       over what is the purpose of the FDA? What actually happened  
3       in this case? All of these facts wouldn't cause an  
4       extremely time consuming mini-trial.

5               It is true that I think some of the documentary  
6       evidence that you're talking about, for instance, the FDA  
7       letter, I don't see in any way how that can ever come into a  
8       courtroom at all.

9               THE COURT: I just read you the Rule of Evidence.

10              MR. BANKSTON: Well, no, I don't think there was a  
11       legal duty to create that letter. That's what I'm saying.  
12       I think there are plenty of documents in this case that were  
13       a legal duty to create. I don't think that letter goes --

14              THE COURT: Why do you not think that?

15              MR. BANKSTON: I don't see any legal statutory  
16       basis to cause that letter to be written. I don't see any  
17       regulatory scheme that causes that letter to be written.  
18       And I think if we all understand the circumstances, it seems  
19       to stretch credulity to think that that letter was created  
20       sua sponte by the FDA. These are things we would obviously  
21       like to explore if that has to come in and, again, things we  
22       don't need to explore.

23              So I do think there are some things that come in,  
24       some things that would under hearsay, but our entire  
25       argument is a 403 argument, and I do believe that it would

1       cause a mini-trial if that happens.

2               THE COURT: All right. Thank you.

3               MR. BANKSTON: Moving on from that, there's also  
4       the issue that so many of these opinions require him to  
5       speculate on what the FDA would have done in the absence of  
6       any specific documentation or technical information that he  
7       can rely on. And these were exactly the kinds of opinions  
8       that were excluded in *Brown v. Medtronic*. Interestingly  
9       enough, that was attached to Exhibit 10 to Defendant's  
10      motion. They take a reading of that case to talk about  
11      Mr. Ulatowski's qualifications, don't really want to apply  
12      the part where it talks about the very opinions he gives in  
13      this case need to be excluded because they are way too  
14      speculative.

15              He has other contradictory opinions about things  
16      like warnings that directly contradict the documents, the  
17      FDA blue book guidance documents that talk about warnings.  
18      And we think in terms of a methodology, if his only  
19      methodology is to review FDA statutory and regulatory  
20      authority and FDA materials to give the opinions about what  
21      the FDA requires, he has to show fidelity to those  
22      materials. If he's not, he's not working under a reasonable  
23      methodology.

24              There's also the large problem in this case of  
25      Mr. Ulatowski's direct personal involvement with the Bair

1 Hugger and that's going to become very difficult to excise  
2 from this case. And we believe this is a matter that raises  
3 significant prejudice. He does have personal contacts with  
4 this product with this company over the course of his  
5 career. He is in fact a 510(k) signatory on a clearance  
6 document for Bair Hugger product. He's been involved with  
7 the product line before.

8 He has, there's actually been during the period in  
9 which Arizant was trying to I guess fight a commercial  
10 damage control mode over some of their competitor's  
11 advertising, they wrote a letter to Mr. Ulatowski.  
12 Mr. Ulatowski says that he thinks by that point he was in a  
13 different job and, thus, would have forwarded the letter to  
14 somebody else, but there's no doubt that he is a recipient  
15 of that letter. The finding was that Mr. Ulatowski himself  
16 is the author of the FDA's warning letter to 3M or I believe  
17 it might have been Arizant at that point regarding burns  
18 caused by the Bair Hugger. Obviously, when we're going to  
19 be talking about overall risk utility versus products,  
20 that's something we're going to be interested in talking  
21 about. To have the person who authored that warning letter  
22 on the burns sitting in the witness stand as a paid  
23 representative of the defendants is a -- creates a really  
24 ripe opportunity for jury confusion.

25 We think it's going to be very difficult for the

1 jury ultimately to know and to really understand whether  
2 Mr. Ulatowski is here as an independent person being paid by  
3 the defendants to give opinions or whether he's here giving  
4 opinions essentially on behalf of the FDA. That is an  
5 extreme danger to the plaintiffs. This is not a speculative  
6 kind of prejudice. And given that his testimony really  
7 offers very little of value, there seems to be no reason to  
8 subject the plaintiffs to that kind of prejudice.

9 Mr. Ulatowski's opinions, really he's had to dial  
10 them back because of all of these prior exclusions. There  
11 used to be a time when Mr. Ulatowski would come to a  
12 courtroom and say FDA 510(k) process is equivalent to a  
13 finding of non-negligent design. It's directly relevant to  
14 plaintiffs' claims. And after being excluded on that point  
15 multiple, multiple times, he's dialed it back to something  
16 that is just not helpful to us. It really doesn't do  
17 anything to us.

18 The times that this Court or at least this  
19 District has admitted FDA testimony, it has been in the  
20 context of where plaintiffs have made specific allegations  
21 of violations of the minimum floor of what a manufacturer  
22 has to do, and those violations going below that minimum  
23 floor is very relevant to a standard of care, at least it  
24 can be in many cases.

25 There's no authority out there, and certainly



1 defendants have cited none that says Bair compliance with  
2 those regulations is in any way relevant to standard of  
3 care. So if it's not relevant to non-negligent design and  
4 product defect, and it's not relevant to standard of care,  
5 it really doesn't do a lot for us in this trial.

6 The last thing I want to talk about with  
7 Mr. Ulatowski is there's sort of a large gray area about  
8 what he may or may not testify about by hooking into certain  
9 parts of his opinion, about is he going to testify about  
10 regulatory matters or not? And I tried to pin him down on  
11 some of these topics at deposition, and his answer was  
12 essentially who knows. And defendant's response to this is,  
13 well, if he's asked to make those opinions then we'll  
14 examine his competence then. And I really don't want that  
15 sort of Damocles hanging over it.

16 So I think another part of the thing that  
17 plaintiffs are asking for in this order is a limitation that  
18 if he's going to testify about anything, it's not going to  
19 be orthopedic surgeries, engineering, biomedical issues.  
20 The only thing he can be qualified at all in is regulatory  
21 testimony. And we don't believe that any of that is going  
22 to be very helpful to us in this case.

23 So unless you have any questions, I'll go ahead  
24 and pass it on over to them, and let them tell you about  
25 Mr. Ulatowski as well. Thank you, Your Honor.

1 MS. AHMANN: Good morning, Your Honors. Bridget  
2 Ahmann for 3M and Arizant in opposition to the motion to  
3 exclude Mr. Ulatowski. May it please the Court, Counsel:

4 I was going to be really, really short because I  
5 thought the presentation would be short, but I feel like  
6 Mr. Ulatowski has been attacked on numerous grounds that are  
7 inconsistent both with what he's saying and what the law  
8 provides.

9 First of all, he is here to talk about FDA  
10 regulations specific to medical device and also to talk  
11 about how 3M, Arizant complied or dealt with those  
12 regulations. The fact is the medical device community is  
13 governed by the FDA. That is the framework within which  
14 they operate.

15 Yesterday, there was a comment, I believe, by  
16 Mr. Farrar about how one of the experts didn't talk about  
17 any standards. He came without talking about any standards.  
18 Well, the fact is Mr. Ulatowski will talk about standards  
19 because that's directly what is applicable in the jury's  
20 consideration of whether or not this company acted  
21 reasonably. Such testimony is necessary.

22 First, I will talk a little bit about  
23 Mr. Ulatowski not that his qualifications have been --

24 MAGISTRATE JUDGE NOEL: Can I interrupt for a  
25 quick second and go back to your opening slide because I

1 think there's a typo or something or I'm confused entirely  
2 about what we're doing here. It's not your motion to  
3 exclude --

4 MS. AHMANN: I'm sorry, in opposition.

5 MAGISTRATE JUDGE NOEL: Okay, thank you. I just  
6 wanted to make sure.

7 MS. AHMANN: They were prepared a long time ago,  
8 so you're right. I'm arguing --

9 THE COURT: If they want him, you'd be getting --  
10 (Laughter.)

11 MS. AHMANN: What Mr. Ulatowski is going to talk  
12 about is not just that little 510(k) that is but what one  
13 glip on what the FDA's exercise of authority is and their  
14 evaluation of medical devices. They run the gamut, and he  
15 was involved at all different stages in medical device  
16 evaluations and that's what he's going to talk about. The  
17 510(k), which is the only thing we've heard about in terms  
18 of the legal authority, there have been courts that have  
19 excluded that type of evidence with regard to the FDA.

20 Specifically, as he says what Mr. Ulatowski is not  
21 going to say. Mr. Ulatowski is not here to say that the  
22 510(k) by itself defines or is preemptive, if you will, on  
23 the question of whether or not the device was safe and  
24 efficacious. What he's going to say is safety and efficacy  
25 go into consideration in the 510 stage.

1           The cases that have held otherwise look at *Lor* and  
2     *Riegel*, which are preemptive cases. They don't deal with  
3     relevance. What they say is you can't make a statement that  
4     the 510(k) by itself establishes that this is safe and  
5     efficacious. So it can't preclude any state claims on it.  
6     That's not the allegation. We're here to talk about whether  
7     or not evidence on the 510(k) is relevant, and we say it is.

8           The other thing as I showed you here, 510(k) is  
9     but a glip. What they've tried to do is they've tried to  
10    glam on to these cases and to try and extend that to go  
11    beyond a 510(k) evidence. In fact, it's interesting because  
12    they presented their own regulatory expert until the FDA  
13    letter came out, and now all of a sudden they want to  
14    withdraw that, and they don't want to talk about the FDA.  
15    So his testimony is relevant not just to 510(k), it's beyond  
16    that.

17           And might I say that we don't agree with those  
18    cases because we think the jury needs to understand what  
19    environment these companies work in and how can you judge  
20    the reasonableness of their behavior in making design  
21    choices, of deciding what risks to talk about if you don't  
22    know the environment with which they operate.

23           In fact, many courts, not just the one cited by  
24    the plaintiffs, and in fact, he refers to them as gabs or  
25    gobs which I take to be many, almost all of the cases

1 emanate out of the MDL mesh litigation in the Southern  
2 District of West Virginia. In those cases, the Judge made a  
3 decision, and he has applied that over and over and over  
4 again in those cases. He has been affirmed as indicated by  
5 the Fourth Circuit. We don't agree with those because we  
6 think there's lots of other cases which have recognized that  
7 in fact FDA evidence is relevant.

8 *In Re Fosamax*, a lay jury cannot be expected to  
9 understand the complex regulatory framework that informs the  
10 standard of care in the pharmaceutical and medical device  
11 industries. Admittedly, that's a drug case, but the fact is  
12 the FDA is who the FDA is, and they regulate both drug and  
13 medical devices. Minnesota law is consistent with that  
14 because the courts have time and again and contrary to what  
15 is suggested, they've actually allowed testimony about the  
16 FDA when the FDA has found that the defendants act in  
17 compliance.

18 *In Kruszka v. Novartis* case, they allowed the FDA  
19 expert to opine on the reasonableness of the defendant's  
20 interactions with the FDA in compliance with FDA  
21 regulations. And here's the important part for us today.  
22 "And such testimony would be helpful to the trier of fact  
23 from a regulatory perspective." And *Kruszka* is not the only  
24 case.

25 *In Huggins v. Stryker*, which involved a medical

1 device, a pain pump, the Court recognized that the device  
2 manufacturer's interactions with the FDA at the 510(k)  
3 clearance were relevant because the jury, they could shed a  
4 light on the considerations by the jury.

5 In *Lillebo v. Zimmer*, which was an orthopedic  
6 case, they allowed the FDA expert to testify as to FDA  
7 processes including the FDA clearance in considering the  
8 reasonableness of the manufacturer's design, testing and  
9 manufacture. Minnesota courts allow this. There really  
10 shouldn't be much question about whether or not this is  
11 relevant and helpful to the jury. This is not confusing.  
12 This is not -- the Court can certainly control the  
13 introduction of evidence to avoid any kind of mini trial.

14 I also want to briefly address some of the  
15 reliability arguments. I'm not going to go into details.  
16 Those were addressed in our papers. Mr. Ulatowski performed  
17 the same type of evaluation that he would have when he was  
18 at the FDA. He reviewed thousands and thousands of pages of  
19 documents and to criticize because him because he forgot  
20 that he had in fact reviewed one particular piece of  
21 evidence is really in excusable. It certainly doesn't go to  
22 the credibility or the reliability of his methodology. He  
23 can be cross examined on that. And, in fact, that would be  
24 the appropriate if counsel thinks that that is important,  
25 but that goes to the weight of his testimony not the

1       admissibility. And I won't even go into the various other  
2       because they're all explained by Mr. Ulatowski.

3               They also complain that he has a conflict of  
4       interest because counsel thinks that he's touched these  
5       cases. First of all, they present no legal authority, no  
6       regulatory authority, nothing on the issue of ethical  
7       obligations of the FDA. But Mr. Ulatowski talked about that  
8       and that's in our brief. He's talked to the Ethics  
9       Committee for the FDA knowing that when he serves as an  
10      expert in cases that there are certain things he can't talk  
11      about, and he doesn't, and he didn't here. There's nothing  
12      to counter that.

13             And even factually all these ethics and all these  
14      biases are founded. Mr. Ulatowski talked about the fact  
15      that he didn't receive the August of 2010 letter because he  
16      would have been at a different department. So counsel says  
17      that he thinks he wouldn't have got it. Well, he knows he  
18      wouldn't have gotten it. He wasn't there. He had moved on.

19             He also didn't -- he was asked about whether or  
20      not he was copied on a letter that dealt with the Bair  
21      Hugger fluid warming. And counsel would like to say that he  
22      evaluated that and that's the same thing as the Bair Hugger.  
23      It's not. It is a fluid warming device. It is not a  
24      patient warming device generally. It is in a totally  
25      different division, which he explained in his testimony.

1           He was not involved in the division that operated  
2           the Bair Hugger and the warming device. He was the fluid --  
3           he was in the division that evaluated the fluid warming  
4           device. And the fact is if counsel would have shown him the  
5           full document, the full document shows that this was not a  
6           forced air warming device at all. It was a completely  
7           different methodology and engineering to do the fluid  
8           warming.

9           And with regard to, there was a letter that he did  
10          send out relative to the burns. And, again, has nothing to  
11          do with the issues in this case, and he can certainly be  
12          cross examined on that if they think it's appropriate.

13          And the final argument is that we should exclude  
14          him from talking about everything else because we don't know  
15          if he's going to talk about everything else. I think that  
16          it probably is best to wait and see what he talks about  
17          before we exclude him. His report was very thorough. And  
18          if his opinions were in there, I think that, you know,  
19          counsel will be hard pressed at the time unless he's drawn  
20          out by other questions from the plaintiffs' side, the fact  
21          is there's no reason right now to sit and talk, theorize  
22          about what he might be asked. Unless the Court has  
23          questions.

24          THE COURT: Ms. Ahmann, are you the person to ask  
25          about what it is that Mr. Bankston was referring to when he



1 was talking about the --

2 MS. AHMANN: FDA letter and moral turpitude and  
3 all of that?

4 THE COURT: Yes.

5 MS. AHMANN: Absolutely not me. You know, I have  
6 to say that, you know, we have not been presented in these  
7 days of arguments about a motion to deal with the FDA  
8 letter. It has been referred to several times using what  
9 Mr. Blackwell would say, I'm not as good as he is at saying  
10 "that horse has left the barn." We are, you know, the FDA  
11 letter is there. There's no doubt that it's going to be  
12 evidence.

13 THE COURT: But have they shared with you whatever  
14 it is that he was --

15 MS. AHMANN: No, this is the first I've heard of  
16 it, so I am definitely not the person to deal with it.

17 THE COURT: I'm sure it was somebody on your side.

18 MR. BLACKWELL: Your Honors, if I may?

19 THE COURT: Yes, please, Mr. Blackwell.

20 MR. BLACKWELL: Just to put this to rest, the  
21 author of that letter was picked up for solicitation roughly  
22 five years ago.

23 THE COURT: Mr. Maisel or Dr. Maisel, M-A-I-S-E-L?

24 MR. BLACKWELL: Whoever signed it. I don't have  
25 the name in mind, Your Honor, on the FDA letter, but he was

1 then returned to his job, given his job back thereafter. So  
2 if this is something we want to talk about from about five  
3 years ago, he was picked up with solicitation. The FDA  
4 restored him to his job sometime thereafter, and that's what  
5 they're referring to the dastardly, horrible --

6 THE COURT: Was he convicted of anything?

7 MR. BLACKWELL: They're saying, yes, and we don't  
8 know, but I expect --

9 THE COURT: Misdemeanor or felony?

10 MR. BLACKWELL: Misdemeanor solicitation.

11 MR. BANKSTON: There were four counts of felony  
12 solicitation all pled down to a misdemeanor.

13 THE COURT: Okay, but the conviction there's 609,  
14 you're talking about conviction.

15 MR. BANKSTON: Correct, Your Honor.

16 THE COURT: My question has to do with conviction.

17 MR. BANKSTON: Yes, my understanding is there are  
18 convictions on the record against him.

19 THE COURT: One misdemeanor?

20 MR. BANKSTON: I actually am not -- I can't speak  
21 to you right now whether those are misdemeanor or felonies.  
22 My understanding was they were felonies, but I don't --

23 MR. BLACKWELL: My goodness. They bring this --

24 THE COURT: Yeah, that's pretty, yeah, well --

25 MR. BLACKWELL: They bring this up. They know

1       it's a misdemeanor solicitation, and at least that's an  
2       understanding of what this is about.

3               THE COURT: All right. Mr. Bankston, I guess  
4       you're the person who brought this all up. Is that what you  
5       were talking about?

6               MR. BANKSTON: Yes, Your Honor.

7               THE COURT: And is it your position that --

8               MR. BANKSTON: It is our position that he is  
9       uniquely vulnerable to continued influence given his  
10      predilection for picking up and exploiting human trafficking  
11      victims off the streets of D.C. That's our position.

12              THE COURT: I have an evidence question for you.

13              MR. BANKSTON: Sure.

14              THE COURT: Calling your attention to Rule 609,  
15      assuming for the moment that it is a misdemeanor prosecution  
16      conviction, is it your -- do you have any authority for  
17      the --

18              MR. BANKSTON: That it would be an admissible --  
19      you're correct, Your Honor. Yes, I do.

20              COURT REPORTER: Don't interrupt, please.

21              THE COURT: Would you just let me ask the  
22      question?

23              MR. BANKSTON: Oh, I'm sorry, yes.

24              THE COURT: That that constitutes a crime of  
25      falsehood?

1 MR. BANKSTON: That solicitation under the  
2 prostitution statute does? Constitutes a crime of moral  
3 turpitude? Was that --

4 THE COURT: No, my question, as you know or should  
5 know, misdemeanors under 609 are admissible if they are  
6 crimes, you know, *crimen falsi*, crimes of falsehood. And to  
7 my, in my experience, a prostitution conviction has not and  
8 is not considered a crime of falsehood. My question to you  
9 is if you have any authority to the contrary?

10 MR. BANKSTON: I thought the determinative issue  
11 was whether it's a crime involving moral turpitude.

12 THE COURT: Well, it's not being impeached. It's  
13 --

14 MR. BANKSTON: Well, I do have the authority on  
15 CIMT.

16 THE COURT: I don't know what "CIMT" is.

17 MR. BANKSTON: Oh, I'm sorry, Crime Involving  
18 Moral Turpitude. I have Eighth Circuit authority on that.

19 THE COURT: All right. Give me a case on that  
20 then.

21 MR. BANKSTON: Sure. That is *Gomez Gutierrez v.*  
22 *Lynch*. That is 2016 Westlaw 362 24 -- excuse me -- 362 427  
23 at \*4. That is the Eighth Circuit in 2016. And I just  
24 wanted to add the reason I'm kind of familiar with that is I  
25 have sort of a parallel practice with some immigration

1 issues and have been recently taught in no uncertain words  
2 do not let your immigration clients plead to misdemeanor  
3 crimes of moral turpitude.

4 THE COURT: All right. Well, let's talk about the  
5 Rules of Evidence. That may be all well and good. 609A  
6 talks about felonies, subdivision 1, imprisonment for more  
7 than one year. And then there is a second subdivision for  
8 non-felony convictions and that ties to a dishonest act or  
9 false statement and that is the codification of the common  
10 law crimen falsi doctrine.

11 MR. BANKSTON: Okay.

12 THE COURT: It doesn't have anything to do with  
13 moral turpitude.

14 MR. BANKSTON: Okay.

15 THE COURT: So are there any cases that you can  
16 cite for the proposition that the sort of conviction that  
17 you are talking about with respect to that employee where  
18 those have been categorized as dishonest or false statements  
19 for purposes of Federal Rule of Evidence 609(a)(2)?

20 MR. BANKSTON: Not standing here now, no, I don't,  
21 Your Honor. That's certainly something I would like to look  
22 into. And to us the more threshold question is not how such  
23 evidence would be admitted, but in our minds, the question  
24 is what is the fundamental reliability of that letter? Is  
25 there anything in that letter that makes us question it as

1 potentially I mean obviously we have basic problems with the  
2 letter itself. We do have problems with the letter of the  
3 author. These are issues that we very well could  
4 potentially raise in trial. And as far as that authority --

5 THE COURT: Well, I'm asking you right now since  
6 you're the one who brought it up and were so exercised about  
7 the moral turpitude.

8 MR. BANKSTON: I absolutely am very troubled by it  
9 and very troubled by the unique vulnerability that a federal  
10 regulator who was allowed to return to that role with such a  
11 predilection is subject to potential influence from outside  
12 sources. I'm very concerned about that.

13 THE COURT: Is there anything else or is that what  
14 you're talking about?

15 MR. BANKSTON: That's what I'm talking about in  
16 terms of those crimes. Correct, Your Honor.

17 THE COURT: Thank you, Mr. Bankston. You may be  
18 seated now. I want to hear from Mr. Blackwell on that  
19 basis.

20 MR. BLACKWELL: Your Honor, just want to make sure  
21 the record is clear that he did not lose his job. He pled  
22 to one of several counts. There was a \$200 fine, and the  
23 rest of the charges were in fact dismissed. And as Your  
24 Honor is well aware, he simply signed on behalf of the  
25 agency, and I'm not seeing the tie-in other than simply

1       wanting to raise this for obvious reasons.

2               THE COURT: All right. Well, let's talk about  
3       Mr. David. Mr. Winebrenner?

4               MR. WINEBRENNER: Yes, Your Honor. Good morning,  
5       Your Honors. I'm Joe Winebrenner on behalf of defendants.  
6       I will be discussing defendant's motions to exclude  
7       Dr. Yadin David.

8               Dr. David's opinions can be separated roughly into  
9       four categories. Defendants have moved to exclude his  
10      opinions in all four in their entirety. They are his  
11      regulatory opinions, his standard of care opinions, his  
12      so-called hazard analysis opinions, and his alternative  
13      design opinions. Of these four categories of opinions, the  
14      only two that arguably address causation issues are the  
15      hazard analysis opinions and alternative design opinions,  
16      and for that reason, I intend to address those first.

17              Dr. David conducted what he calls a hazard  
18      analysis of the Bair Hugger system. This consisted of an  
19      examination of a used Bair Hugger device as well as a review  
20      of a small selection of documents and literature. And based  
21      on this work, Dr. David claims to conclude that the Bair  
22      Hugger more likely than not increases the risk of surgical  
23      site infections in orthopedic surgeries. We address in our  
24      briefing a number of reasons why this opinion should be  
25      excluded. I'm going to focus on just a few of the high

1 level points today.

2 First, Dr. David is not qualified to opine on the  
3 clinical risks of the Bair Hugger system. And by "clinical  
4 risks of the Bair Hugger system," I'm talking about medical  
5 causation because that is what his opinion touches on.

6 Dr. David is a biomedical engineer by trade. He's  
7 not a medical doctor. He is not a clinician. And although  
8 Dr. David has participated in a committee, the Medical  
9 Technology Evaluation Committee in which he in the context  
10 of a committee makes purchasing recommendations to his  
11 employer hospital. Dr. David is not the one performing the  
12 clinical risk assessments of the devices that are being  
13 evaluated in that committee. He defers that task to others  
14 who are more appropriately qualified.

15 Now, plaintiffs contend that we're wrong in that  
16 regard and that Dr. David performs these clinical risk  
17 assessments all the time, but the record does not support  
18 that argument.

19 Dr. David in his deposition testified to the  
20 makeup of his Medical Device Evaluation Committee. He says  
21 that "my committee consists of many representative  
22 stakeholders, physicians, nurses, purchasers,  
23 administrators, safety officers, risk control and quality  
24 control professionals, and facilities engineering,  
25 biomedical engineering and sterile processing supplies."



1           And he goes on: "So the committee was  
2     representing so many expertise, and I was in the position  
3     where I had to receive their input and derive recommendation  
4     to the hospital management if a device is beneficial with  
5     lower risk than what's being used today."

6           Now, to avoid any ambiguity with respect to  
7     Dr. David's role in this process, he was asked:

8           "In performing your work for the hospitals, do you  
9     rely on physicians and nurses to provide you with  
10    information about clinical risks and benefits?

11          Answer: On the clinical side, yes."

12          So the record does not support plaintiffs'  
13    contention that Dr. David performs these clinical risk  
14    assessments of devices all the time. He relied on others to  
15    do that.

16          What Dr. David does in his report is different.  
17    He does not rely on anyone to assess clinical risks and  
18    benefits of the Bair Hugger device. He does that himself,  
19    and this is problematic under Rule 702 not only for  
20    qualifications purposes but also because it is a departure  
21    from his ordinary methodology. In the hospital context,  
22    Dr. David relies on others to assess clinical risks of the  
23    device, but when he is retained as an expert in litigation,  
24    he is a one-man show. He does everything by himself, and  
25    Rule 702 does not allow this.

1           The second piece with regard to Dr. David's hazard  
2           analysis that I want to raise is a disconnect between the  
3           methods that he says he employs and the conclusions that he  
4           purports to reach. In the hospital setting, Dr. David's  
5           committee evaluates devices for purposes of making  
6           purchasing recommendations not for the purposes of  
7           evaluating medical causation, whether a device medically  
8           causes a particular outcome. And the factors that are  
9           considered under these two situations are quite different.

10           In the context of a purchasing decision, a decision  
11           may be made based on factors that result in conservative  
12           decision making, factors such as public health  
13           considerations or just the general risk aversion of a  
14           hospital such that a hospital may choose to avoid a  
15           particular device because of questions about safety or  
16           effectiveness even when there is not a sound scientific  
17           basis to support those questions. And those types of  
18           factors have no role in a medical causation inquiry under  
19           Rule 702.

20           On top of this, Dr. David applied or chose not to  
21           apply the industry standard overall methodological framework  
22           for assessing the risk of medical devices. That standard is  
23           ISO 14971. Dr. David opted instead to employ a methodology  
24           of his own creation. It was one that he adapted from the  
25           miter standard, which he had used in the past in the

1 hospital setting to evaluate or to prepare for a disaster,  
2 disaster preparedness like the shutdown of the electrical  
3 grid, for example. And plaintiffs do not demonstrate how  
4 Dr. David's methods fit or can reliably lead to medical  
5 causation opinions, which is the purpose of his opinions in  
6 his report.

7 The last issue I want to discuss with regard to  
8 his hazard analysis is a series of issues, the problems with  
9 the steps that Dr. David took in his analysis. Plaintiffs  
10 contend that he reviewed an extensive body of literature,  
11 testimony, documents, as well as an examination of the  
12 device itself, but Dr. David did not review an extensive  
13 body of literature. He reviewed only 14 published articles,  
14 all of which reached conclusions that support, that were  
15 relatively favorable to the opinions that he reached.

16 Now, Mr. Blackwell and Mr. Goss discussed those  
17 articles over the past two days, and they demonstrated that  
18 none of them determined causation and none of them even  
19 reach a valid association with the Bair Hugger. But even  
20 setting the substantive shortcomings of those articles  
21 aside, Dr. David's actual methods in employing the  
22 literature review warrant exclusion of his testimony. He  
23 did not review a single study that was unfavorable to his  
24 conclusions. He didn't even acknowledge a single study that  
25 recognized that the Bair Hugger does not increase the risk

1 of infection, and we've heard all about those studies over  
2 the past two days. Courts around the country have  
3 recognized that expert witnesses cannot opine on causation  
4 based on a literature review that selectively includes only  
5 the most favorable stuff.

6 *In Re Rezulin* is an example. The Court recognized  
7 if the relevant scientific literature contains evidence  
8 tending to refute the expert's theory and the expert does  
9 not acknowledge or account for that evidence, the expert's  
10 opinion is unreliable. And in that particular case, the  
11 Court concluded that the scientists have discussed only the  
12 evidence that they believed would advance the plaintiffs'  
13 position. Their reports cannot be said to reflect the same  
14 level of intellectual rigor that characterizes the practice  
15 of an expert in the relevant field, and we would submit that  
16 the situation is no different with regard to Dr. David.

17 In a similar manner, Dr. David did not conduct an  
18 extensive review of documents in forming his opinion. The  
19 Bair Hugger is a product that has been on the market for  
20 30 years. There's 30 years of regulatory history.  
21 Dr. David purports to opine on clinical risks of infection  
22 that are not generally accepted in the scientific community,  
23 yet he reviewed only 64 3M produced documents.

24 Now, plaintiffs would take the position in their  
25 response that the quantity of documents that Dr. David

1 reviewed does not matter but rather it's the quality of the  
2 review, but that really just begs the question who is  
3 evaluating these documents and determining which ones are of  
4 sufficient quality to be sent to Dr. David?

5 And the last building block, so to speak, of  
6 Dr. David's hazard analysis opinions was his examination of  
7 the Bair Hugger, and we've heard about that. Dr. David  
8 examined a used device that plaintiffs' counsel purchased  
9 off of eBay.com, and which we've seen in the papers, and  
10 we've heard during the hearing the plaintiffs are  
11 affirmatively contending was not even functioning properly  
12 at the time Dr. David examined it.

13 And so plaintiffs don't demonstrate how an  
14 examination of a device of this sort can possibly support an  
15 opinion on medical causation. So these are all red flags  
16 with regard to Dr. David's hazard analysis opinions, and we  
17 would submit that they warrant exclusion of his opinions in  
18 full.

19 The next piece I would like to address relates to  
20 Dr. David's alternative design opinions. He identifies a  
21 number of other patient warming devices that are on the  
22 market and as well as some early stage design concepts that  
23 have been considered in relation to the Bair Hugger, and he  
24 asserts that these are feasible and safer alternative  
25 designs.

1           There are two major problems with this opinion.  
2           The first is that Dr. David includes conductive warming  
3           devices in his opinion. Devices like the VitaHEAT UB3 and  
4           the Tablegard System, which incorporate conductive warming  
5           technology. This Court has already concluded that  
6           conductive warming technologies are not viable alternative  
7           designs to the Bair Hugger due to the different technologies  
8           that they employ. And so those opinions out of the gate  
9           should be excluded.

10           The second problem with Dr. David's alternative  
11           design opinions is broader, and it touches on all of his  
12           proposed alternatives. And that problem is that he offers  
13           absolutely nothing other than his own say-so that any one of  
14           these proposed alternatives is actually safer. He performed  
15           no testing, and he offers no data whatsoever that could  
16           possibly be the basis of a contention that any one of the  
17           devices that he identifies is actually safer, and he  
18           concedes he has no such data.

19           He was asked in his deposition, "Is there any  
20           clinical data you're aware of that would suggest there's a  
21           difference in infection risk between the Bair Hugger device  
22           and any other patient warming device that you've identified  
23           in your report?

24           Answer: I didn't find it so everything that I did  
25           is in my report."

1           So Dr. David concedes he has no objective data to  
2           support any of his alternative design assertions. And in  
3           fact on the flip side, defendants have proffered that 2017  
4           Cleveland Clinic study, which Mr. Gordon discussed  
5           yesterday. And in that study, over 5,000 surgeries were  
6           analyzed, half of which had been performed with a Bair  
7           Hugger and half of which had been performed with the Stryker  
8           Mistral air device, which is one of Dr. David's proposed  
9           alternatives and which incorporates a HEPA filter. And the  
10          results of that study showed that there was no statistically  
11          significant difference between infection rates of the Bair  
12          Hugger group and the Mistral air group. And so not only  
13          does Dr. David lack any objective support for his  
14          alternative design assertions, the only comparative evidence  
15          that exists contradicts his opinions. And so for those  
16          reasons, we would submit that his alternative design  
17          opinions should be excluded as well.

18                 Now, with regard to the regulatory and standard of  
19          care opinions, I had intended to rest on the papers given  
20          the fact that they are, that these are non-dispositive  
21          issues in a hearing that's focused primarily on causation,  
22          but I just want to make a couple of points with regard to  
23          Dr. David's regulatory opinions so that the Court can  
24          contrast his qualifications and methods to Mr. Ulatowski's.

25                 Dr. David is not a regulatory expert. He's a

1 biomedical engineer. He's never worked for the FDA, in  
2 contrast to Mr. Ulatowski who has decades of experience  
3 within the FDA making actual wholesale regulatory  
4 determinations. Now, plaintiffs rely on some advisory  
5 panels that Dr. David has sat on in the past. And they  
6 assert that his experience with these advisory panels  
7 qualify him to render regulatory opinions but that's really  
8 not the case.

9 Dr. David is never outside the context of  
10 litigation, made the types of regulatory analyses that he  
11 purports to make in his report. His experience on the  
12 advisory panels has been in the context of him providing  
13 biomedical engineering expertise on issues that the FDA  
14 specifically raised with him. He's not on any advisory  
15 panel determining substantial equivalence or determining  
16 regulatory compliance, which are the very issues that -- the  
17 very regulatory issues that he addresses in his report. And  
18 so we would submit that the Court or that Dr. David is not  
19 qualified to opine on regulatory matters.

20 And with that, Your Honors, unless the Court has  
21 any questions, I think we'll rest on the papers.

22 MAGISTRATE JUDGE NOEL: I just have one. The  
23 Cleveland Clinic Study that you referenced comparing the  
24 HEPA filtered device to the non-HEPA filtered Bair Hugger,  
25 is that one of the nine studies that I was asking --



1 MR. WINEBRENNER: I don't think it's in that list  
2 of nine. That particular study appears as Exhibit 10 to our  
3 motion to exclude Dr. David, which is ECF No. 768-1.

4 MAGISTRATE JUDGE NOEL: Thank you.

5 MR. WINEBRENNER: Thank you, Your Honors.

6 THE COURT: Thank you, Mr. Winebrenner.

7 Go ahead, Mr. Bankston

8 MR. BANKSTON: All right, Your Honors, I think I'm  
9 going to start with alternative design because I think  
10 that's the most important issue before us today, and I want  
11 to start to go down the four devices.

12 The first being the Vita Heat, which is resistive  
13 mattress design, and we fully understand the Court's prior  
14 order. Obviously, we disagree with it, but we absolutely  
15 understand it. And the Court's order premised on the idea  
16 that the resistive mattress was too radical a departure of a  
17 kind of technology. And from the order the language was you  
18 can't change a Bair Hugger into a Vita Heat. That's the  
19 idea is it's not like you can make a series of design  
20 changes then a Bair Hugger becomes a Vita Heat.

21 While Dr. David in his report describes why he  
22 thinks it's a substantial alternative design not a  
23 substantially different product, we understand the Court's  
24 order, and I'm not going to litigate it today. But with  
25 respect to the Tablegard product, the Tablegard product is

1 something that the Bair Hugger could become quite easily,  
2 and in fact is something that 3M explored turning the Bair  
3 Hugger into.

4 I direct you to look at Dr. David's report between  
5 the pages of 37 and 40 where he talks about, first, 3M's  
6 white board designs on how to create a closed recirculating  
7 air system. In other words, right now the Bair Hugger  
8 exhausts its air back into the environment. But what if it  
9 recirculated it back into the machine and refiltered the air  
10 and kept it in a closed loop? 3M did white board designs to  
11 try to figure out how to do this, and this was something  
12 they were very much exploring.

13 The Berchtold Tablegard is a practical realization  
14 of that design concept. If you want to take the Berchtold  
15 Tablegard apart and the Bair Hugger apart, they are  
16 identical. They are plastic enclosures that contain a  
17 blower unit, a forced air blowing unit, a heating element, a  
18 temperature sensor, and then a plastic coupling that directs  
19 the forced air into a hose, just like the Bair Hugger. That  
20 hose, just like the Bair Hugger, travels to an enclosure, a  
21 coverlet in the case of the Bair Hugger. Now, in the Bair  
22 Hugger, I believe it's cotton and polyurethane that makes  
23 the blanket and has perforations and it exhausts air out.

24 In the case of the Tablegard, it's a vinyl that's  
25 enclosed. And then at the end instead of an exhaust system,

1       there's a tube that goes right back into the machine. The  
2       Tablegard has done this by integrating it into a surgical  
3       table itself. Instead of making it a disposable item or  
4       something that's reusable like a resistive mattress where it  
5       has to be taken washed somewhere, it's actually part of the  
6       surgical setup, and it does this by having a constant flow  
7       of forced air through the vinyl design. And another benefit  
8       of this is that it maintains pressure control because the  
9       actual air pressure can change throughout the unit.

10               So you can easily make a Bair Hugger a Tablegard,  
11       and they've actually explored doing it. And the method in  
12       which the Tablegard heats the patient is well established.  
13       It is true that unlike the Bair Hugger, which is primarily  
14       convective, minorly conductive, the Tablegard through its  
15       design of making it recirculated becomes primarily  
16       conductive and secondarily convective. But the method in  
17       which it warms patients has been shown in studies conducted  
18       by Dr. Sessler to be equally effective at raising patient  
19       temperatures.

20               Now, it's true that there's not going to be a  
21       study out there, nobody has done an RCT yet at all, of  
22       course, comparing the Bergland Tablegard to the Bair Hugger  
23       in terms of infection rates. But the Bergland Tablegard  
24       removes every mechanism that the plaintiff has identified as  
25       causing these infections. If this device can not introduce

1 air into the room, then it clearly can not affect airborne  
2 contamination.

3 It is true that there is not an RCT on that, just  
4 like there's not an RCT saying that the Bair Hugger causes  
5 infections. But with Dr. David's experience and  
6 understanding of biomedical engineering, I think he can say  
7 when the device functionally removes the only mechanism that  
8 is being identified as the defect, that device is going to  
9 be safer than the Bair Hugger in that respect. So that  
10 design is something that we feel is very much on the table  
11 because that is something that 3M itself has even looked at.

12 With respect to the other forced air warming  
13 devices, particularly the Mistral, I think what 3M is  
14 missing here is the reason the Mistral is a better product  
15 in our mind is not primarily because of a HEPA filter, which  
16 Dr. David does believe from his engineering background is  
17 going to be beneficial.

18 But even Dr. David keys on to a point that Judge  
19 Ericksen raised, which is that the presence of a filter,  
20 even a more effective filter is not going to have any effect  
21 on the amount of heat being put into the environment and  
22 whether that mechanism of injury still continues. So it's  
23 not an optimal choice just to put a HEPA filter on the  
24 device.

25 The reason the Mistral is being advocated by

1 Dr. David primarily is because it has a conspicuous warning  
2 communicated to the manufacturer, and it's one of these in  
3 the first pages of the manual with a big triangle with a  
4 huge exclamation point saying that clinicians should take  
5 into account the possibility of airborne contamination when  
6 using this unit in surgeries. And Dr. David's contention is  
7 that kind of warning would have provided a clinician a  
8 reasonable basis to make himself aware of the science  
9 surrounding this device and make his own clinical judgments,  
10 and he believes given his experience in the creation and  
11 regulation of warnings that it was an adequate warning.

12 So the Mistral really goes more towards  
13 plaintiffs' marketing defect claim than it does its design  
14 defect claim, and so as an alternative design, it's an  
15 alternative marketing design first and foremost. So those  
16 are the alternative designs that he really talks about. And  
17 I do believe that those are well supported and very well  
18 discussed in his report as well.

19 I'd like to move on a little bit to his  
20 methodology, particularly the idea of a clinical hazard  
21 review. And, first, just a bit of law. We cite *Taylor v.*  
22 *Danek Medical*, which is an excellent discussion of what a  
23 biomedical engineer is. And biomedical engineers, according  
24 to that case, discuss "the proper design and implementation  
25 of studies to determine the nature and magnitude of patient

1 risks and the extent to which those risks are realized in  
2 clinical practice." That's what Dr. David has done for as a  
3 biomedical engineer for over 30 years. He has more  
4 qualifications than the usual biomedical engineer because we  
5 hear about his participation in something called the Medical  
6 Technology Evaluation Committee, he's actually the creator  
7 and director of that. That committee evaluates the clinical  
8 risk of medical devices for the Texas Medical Center, for  
9 the largest conglomeration of hospitals in America. And he  
10 has pioneered the field of medical device evaluation for  
11 hospitals. His qualifications have been grossly undersold.

12 He's also the chair of clinical engineering for  
13 the International Federation of Medical Engineers. He's  
14 been given the Lifetime Achievement Award from the American  
15 College of Clinical Engineering, and he continues to provide  
16 regulatory and clinical evaluation to the Texas Medical  
17 Center. His methodology was discussed as being a one man  
18 show and does not like what he does in normal fields and  
19 that's just not true because in this case, his opinion  
20 discusses and relies heavily on the findings provided to him  
21 in the reports of Dr. William Jarvis and Dr. Jonathan Samet,  
22 and these clinicians and epidemiologists input is part of  
23 what he would do in the normal field as well.

24 He discusses in his report that his review in this  
25 case was in fact far more rigorous than what he would

1 normally do in his every day activities, particularly  
2 because he's given access to documents that he would not  
3 normally have access to that other medical device evaluators  
4 and hospitals just simply don't have access to. So his  
5 performance of his job here was fundamentally the same that  
6 he did at the Texas Medical Center for 30 years, and he  
7 talks about that extensively.

8 They claim in that methodology that he didn't look  
9 at any studies that were unfavorable. In fact, I believe I  
10 heard was he didn't examine a single study that was  
11 unfavorable to the plaintiffs' position and that's just not  
12 true. If you check into his report, and I have to pull the  
13 page number on here, I believe it was page 20. That's part  
14 of where he begins the discussion of the scientific  
15 literature that was used to validate the Bair Hugger and  
16 sell it to the FDA essentially as a safe product.

17 Moreover, he talks in his section in his finalized  
18 opinions is a discussion about defendant's reliance on the  
19 materials, what they relied upon, particularly in the terms  
20 of the testimony from their corporate representative, their  
21 clinical director and their director of R&D, that the nature  
22 and findings of the studies they relied upon were not  
23 sufficient that a reasonable medical device company would  
24 have known that those studies were underpowered and not  
25 sufficient to provide a safety statement of the Bair Hugger.

1 That's all there, so I'm not sure why we're hearing that he  
2 didn't discuss in any way negative studies.

3 There's also the bit about we obviously agree that  
4 an expert doesn't have to review every piece of literature,  
5 and this is very different and distinct from the situation  
6 we talked about yesterday with Dr. Ho where he just abjectly  
7 failed to review any of the literature. And so if there's a  
8 study that, you know, there's studies that Dr. David didn't  
9 review or that he was familiar with through his deposition  
10 rather than on his reliance list, these are matters of  
11 weight and not admissibility.

12 The same is true is when you talk about not enough  
13 documents, Dr. David specifically requested what he wanted,  
14 and he wanted the kinds of things that ultimately  
15 Mr. Ulatowski didn't review like 510(k) decision making  
16 documents, and instead of reviewing pages upon pages of  
17 clearly irrelevant materials, yes, Dr. David reviewed the  
18 most important materials in the case. So we really don't  
19 think that that's an issue of methodology at all.

20 And then I do want to talk about his  
21 qualifications of regulation. It's an interesting position  
22 because we, you know, we designated Dr. David and primarily  
23 for his engineering opinions but prepared for regulatory  
24 opinions. Strangely enough, as a defendant to a  
25 traditionally do, he was a reactive. We knew they were



1 going to offer FDA opinions. We needed, although, we don't  
2 ever think they should be admissible, We needed somebody in  
3 case this Court decides it is admissible, and that's what  
4 he's here to do. We never wanted to go down the road of the  
5 FDA and have to deal with that in this trial.

6 But in terms of his qualifications to talk about  
7 that, we talk about past participation with the FDA. He is  
8 currently the chair of the FDA's Good Manufacturing  
9 Committee, the Good Manufacturing Practices Committee. He  
10 sits on the Orthopedic Medical Device Panel. Another one of  
11 his FDA titles is senior biomedical research reviewer. They  
12 said he's never made the regulatory analysis Mr. Ulatowski  
13 has made. That's not really true either because Dr. David  
14 testifies about it and it's in his report that he has made  
15 510(k) reviews for the FDA. He has been asked to do that.  
16 It would seem to be defendant's position that unless you  
17 were employed by the FDA and drew a paycheck from them, you  
18 can't give regulatory testimony and that clearly can't be  
19 the law. Dr. David is perhaps the single most qualified  
20 person who is not employed by the FDA. I can't even  
21 contemplate a way a person would become more qualified  
22 without becoming a senior member of the FDA.

23 He's also currently the regulatory advisor to the  
24 Texas Medical Center. He's written a textbook on these  
25 issues, on regulatory compliance. And he's been repeatedly

1 upheld on this issue.

2 I do want to discuss the one time he got struck on  
3 the issue of FDA and regulation. And there's a case called  
4 *Stevens, Stevens v. Stryker*. Now, the many cases in which  
5 he's been approved on this went swimmingly for him because  
6 they had a great report and everything. The problem was  
7 with Stevens, he was designated primarily as an engineer off  
8 the bat, and what the plaintiffs tried to pull at the last  
9 minute is trying to boot strap some FDA opinions last  
10 minute. And as the Court says in the opinion, there's  
11 nothing in the text of his report that says he has FDA  
12 qualifications. The situation is radically different here,  
13 and so we don't think there's a qualifications issue.

14 I think that covers the bulk of their argument  
15 there. It's pretty well-briefed in the papers, but if you  
16 have any other questions, I'd be happy to answer them.  
17 Thank you, Your Honor.

18 MAGISTRATE JUDGE NOEL: Thank you.

19 THE COURT: We'll take a morning recess,  
20 15 minutes.

21 (Morning recess at 10:57 a.m.)

22 (11:15 a.m.)

23 (IN OPEN COURT)

24 THE COURT: Please be seated. Judge Noel has a  
25 criminal duty matter so he'll join us when he's able. Is

1       there any response on the David or did you want to move  
2       right to your argument on summary judgment?

3               MR. WINEBRENNER: We have nothing further on  
4       Dr. David.

5               THE COURT: Anything on this side before we go to  
6       summary judgment? All right. Mr. Hulse.

7               MR. HULSE: Good morning, Your Honors.

8               THE COURT: Good morning.

9               JUDGE LEARY: Good morning.

10              MR. HULSE: As we wind up this third day, I want  
11       to thank, of course, both the Court and the staff here for  
12       the time and attention that you've given to this matter.

13              THE COURT: You should really thank the court  
14       reporter.

15              MR. HULSE: Believe me, Maria has worked some long  
16       days, and we very much appreciate it.

17              THE COURT: She's got because there was the  
18       request for daily transcript, there are people working down  
19       below the scenes too. I say "down" because they're below  
20       our floor.

21              MR. HULSE: And I know we're all very grateful to  
22       them too.

23              COURT REPORTER: Thank you.

24              MR. HULSE: I'd like to start where Mr. Blackwell  
25       began with the Seventh Circuit statement in the *Rosen* case.

1 The statement that was echoed in the *Bausch & Lomb MDL* and  
2 has been echoed many times when courts exclude experts as a  
3 prelude to summary judgment and that's that the law lags  
4 science. It doesn't lead it. The courtroom is not the  
5 forum to advance new scientific theories. It's not the  
6 place for scientific guesswork even of the inspired sort.

7 And what we've heard from the plaintiffs and their  
8 experts is not real science. It's courtroom science. It's  
9 science opinions that haven't been expressed outside of the  
10 courtroom. Opinions that have been roundly and soundly  
11 rejected by authorities that both sides agree are reliable,  
12 like the international consensus, recently rejected by the  
13 FDA, rejected by numerous authorities who have reviewed  
14 exactly the same literature about this product that's been  
15 out there for 30 years, been used in 200 million surgeries,  
16 used in 50,000 surgeries a day, and is trusted by the  
17 overwhelming majority of anesthesiologists, orthopedic  
18 surgeons, and people in the medical profession.

19 The general causation question here is does the  
20 Bair Hugger system cause prosthetic joint infections or deep  
21 joint infections, in the plaintiffs' phrase? It's not does  
22 it in theory? Can it? Is it possible? If there is one  
23 lesson that we can take away from the *Glastetter* decision  
24 it's that a theory and even a beautiful theory, a theory  
25 that seems to make all the sense in the world, which

1 plaintiffs' doesn't here, but what the *Glastetter* case said  
2 is even where the chain of medical reasoning appears sound,  
3 it's major premise still must be proven, and it must be  
4 proven by valid scientific evidence. When  
5 inferences of causation are going to be drawn, they cannot  
6 be based on ipse dixit. They cannot be based on theory.  
7 They must be based on actual evidence that the Bair Hugger  
8 system causes prosthetic joint infections in the real world.  
9 That's what *Glastetter* said. And there's no real dispute  
10 here that expert testimony is required for general  
11 causation.

12 The *Lipitor* case did us all a service and did a  
13 50-state survey that goes on for about 15 pages in the  
14 opinion and doesn't cite just one case for jurisdiction. It  
15 cites multiple cases. In fact, it cites at least two cases  
16 from Minnesota.

17 The *Willard* case, which we cite in our briefs,  
18 also talks about Minnesota law. It says where is it that  
19 you don't need an expert to get to medical causation? Those  
20 circumstances would include an immediate onset of symptoms  
21 that naturally follow from an accident. So that's a car  
22 accident. Somebody is injured in a car accident, for  
23 example, or a complete lack of any other possible cause.

24 Clearly, when you're talking about things like  
25 prosthetic joint infections, you're talking about multiple

1 possible causes, many possible causes. Most prominently,  
2 the patient's own skin. So in those circumstances, the  
3 plaintiffs must have expert testimony to demonstrate general  
4 causation, to carry their burden to show that they can get  
5 past this point and on to specific cause.

6 Now, I don't know what plaintiffs are going to get  
7 up here and say in response to me, but in their papers, they  
8 have agreed that they need Dr. Samet, Dr. Jarvis or  
9 Dr. Stonnington to get them to general causation. In their  
10 opposition to our brief, they say about Dr. Elgobashi that  
11 he may be used to show the mechanism by which the Bair  
12 Hugger increases the risk of infection. We're talking about  
13 mechanism. We're talking about over on the left hand side  
14 of the joint or gap. The experimental theoretical side.  
15 Cases, and we've cited many of them in our briefs. We've  
16 shown them to you. That's not enough to get to general  
17 causation. *Glastetter* says that too. And plaintiffs in  
18 their briefs don't contend that Dr. Elgobashi gets them  
19 there.

20 In fact, about Dr. David, they don't even mention  
21 Dr. David in their opposition to summary judgment, not one  
22 time. They're not contending that he and his risk analysis  
23 can get them to general causation nor Mr. Buck nor  
24 Mr. Koenighofer. It's Samet, Jarvis and Stonnington, and  
25 that makes sense.

1           This is a medical injury case, involves complex  
2           medical injuries. If inferences are going to be made about  
3           causation based on the evidence, it's going to have to be  
4           made by qualified medical professionals.

5           And we've talked about these cases several times.  
6           MDL after MDL has held and then *Glastetter* says the same,  
7           causation has to be based on more than just possibility.  
8           You have to show that this mechanism, this mechanism that  
9           they're advancing here really plays out in the real world.  
10          And so what do Samet, Jarvis and Stonnington, the three  
11          medical experts on the plaintiffs' side rely on to show that  
12          this theory that they have actually plays out and causes  
13          infections in the real world?

14          Well, Dr. Samet said it best, in reference to the  
15          McGovern study, he said, "absent the quantitative estimate  
16          from that paper, it would be -- well, there would be a quite  
17          plausible mechanistic basis for increased risk. There would  
18          not have been an association in the real world."

19          And why do you need an association? What The  
20          Reference Manual on Scientific Evidence says is that the  
21          Bradford Hill factors, the factors that purportedly Samet  
22          used, and plaintiffs contend also that Jarvis and  
23          Stonnington used something at least close to Bradford Hill,  
24          they are employed only after a study finds an association to  
25          determine whether that association reflects a true causal

1 relationship. If you don't have an association, you stop.  
2 That's it. You are on the side of, at best, theory,  
3 plausibility. You don't get to an inference of general  
4 causation.

5 In fact, The Reference Manual goes on on the same  
6 page in a footnote. Notes that some experts attempt to use  
7 the Bradford Hill factors to "support the existence of  
8 causation in the absence of any epidemiologic studies  
9 finding an association." And The Reference Manual says  
10 quote, "there may be some logic to that effort but it does  
11 not reflect accepted epidemiologic methodology." If you're  
12 going to infer causation as a medical expert, you have to  
13 have an association.

14 And when you're basing that association on an  
15 observational study, this is what The Reference Manual has  
16 to say. The Reference Manual talks about the weaknesses of  
17 observational study. There's a susceptibility to bias and  
18 confounding. And so this is what The Reference Manual says.  
19 If you're going to use an observational study or studies to  
20 make a conclusion of causation as Samet, Jarvis and  
21 Stonnington did here. You want to see the association  
22 across multiple observational studies with different  
23 designs, difference kinds of subjects, and done by different  
24 research groups.

25 And why is that? Because of the susceptibility of



1       confounding. If we get consistent results across multiple  
2       observational studies, multiple facilities, it makes it less  
3       likely that an association that was found was the product of  
4       bias or confounding.

5               And you have to take into account, the manual  
6       says, the effects of confounding variables. You have to use  
7       appropriate methods to do it, including comparing small  
8       groups that are relatively homogenous with respect to  
9       confounders, which is what Dr. Holford and Dr. Borak did  
10      when they showed the McGovern study, when you control for  
11      thromboprophylaxis, and you control for antibiotics, any  
12      purported association vanishes. And Mark Albrecht, the  
13      co-author, the Augustine employee, agreed. He didn't even  
14      have to do the number crunching. He knew that that was the  
15      case.

16             And you have to take into account plausible  
17      explanations for the purported association. What are the  
18      alternative explanations that could explain this? The  
19      introduction of a major infection control initiative, change  
20      in antibiotic, change in thromboprophylaxis. These are the  
21      things you have to do in order to make an inference of  
22      causation.

23             So does McGovern find an association between use  
24      of the Bair Hugger system and increase in deep joint  
25      infections? On its face, it does not. There has been much

1 misreading of this study in this courtroom.

2 What McGovern says is we had two periods of time.  
3 We had a period of time with the Bair Hugger system, and we  
4 had a period of time with the HotDog system. And there was  
5 a higher rate of infections that we found during the HotDog  
6 period. The association they found was between the period  
7 --

8 THE COURT: During the HotDog period?

9 MR. HULSE: I'm sorry, I misspoke. The higher  
10 rate of infection in the Bair Hugger period. They found the  
11 association between the period and the higher rate, and so  
12 that's why they came to this statement. This study doesn't  
13 establish a causal basis for this association. We can't  
14 attribute this higher rate in the Bair Hugger period to the  
15 use of the Bair Hugger. And why not? Because the data are  
16 observational, may be confounded by other infection controls  
17 instituted by the hospital. It notes the change to the  
18 antibiotic and the thromboprophylaxis.

19 And you may remember the drafts of Figure 7 from  
20 McGovern that show the spike during the Rivoraxaban period.  
21 It says, "in addition, we were unable to consider other  
22 factors that have been associated with SSI, including blood  
23 transfusion, obesity, incontinence, and fitness for surgery,  
24 which have been identified elsewhere as important predictors  
25 for deep infection."

1           So we know these are potential confounders here.  
2           That's why we are not able to attribute this increase to the  
3           Bair Hugger. It's not right to say this finds an  
4           association between the Bair Hugger system and deep joint  
5           infections. That's not what it finds, and they don't say  
6           it. And you don't have to take my word for it. Let's take  
7           Dr. Reed.

8           Plaintiffs have said that the study authors stand  
9           by the study. They stand by it, and in fact they do. Now,  
10          we didn't have the documents to show Dr. Reed about the  
11          transposition of the one infection in the data manipulation,  
12          but he stood by his conclusions. He stood by what he stated  
13          in the paper. Dr. Reed is the senior author. Why in the  
14          paper did you say this study does not establish a causal  
15          basis for the association? He says because it doesn't. It  
16          doesn't establish a causation or study.

17          But here's a question that plaintiffs' counsel  
18          asked him. "Did any of your studies, includes McGovern,  
19          indicate that the increase in bacteria around the surgical  
20          site increases the likelihood of periprosthetic joint  
21          infection by the susceptible host?"

22          And this is key how he explains what the McGovern  
23          study found. "So we have shown," this is his answer -- "So  
24          what we have shown is an association with, you know, what we  
25          did for a period of time and then we changed. And then we

1 had a change in infection rates with the caveats that we had  
2 changes to our practice. Apart from that, as we have  
3 detailed and as we have put in our paper."

4 In other words, we made some significant changes  
5 to our practice. One of those changes was we switched over  
6 to the HotDog. And when we made those changes, we found a  
7 decrease in infection rates. That's the association they  
8 found.

9 What they're reporting here is we know that things  
10 like obesity, fitness for surgery, those are known to be  
11 factors. We're also offering you here a new data point, a  
12 new possibility that the Bair Hugger Forced Air Warming  
13 should be considered as a factor too. But they're not  
14 finding an association between that increase and the Bair  
15 Hugger. They're not attributing it to the Bair Hugger.

16 And so it's not surprising too given these  
17 limitations that there has been strong criticism of the  
18 McGovern study. The Duke Infection Control Outreach  
19 Network, which is a major resource for practitioners in this  
20 area have said no adequately powered, properly controlled  
21 statistically significant reproducible studies has been  
22 published demonstrating an increased risk of SSI to be used,  
23 due to be used of forced air warming devices.

24 Professor Sikka, Dr. Sikka in his published  
25 article in The Journal of Bone and Joint Surgery, which was

1 a full literature review in 2014, said that they recognize  
2 McGovern failed to account for age or medical comorbidities.  
3 Why is this important? Because everybody who practices in  
4 this area knows how important this stuff is failed to  
5 account for other infection control measures implemented  
6 during the study period, and the co-author was an employee  
7 of a conductive warming company. That was Albrecht, an  
8 employee of Augustine. And, interestingly, here's a medical  
9 professional scholar published in a journal who considers  
10 that a relevant criterion to assessing the scientific  
11 validity, trustworthiness and reliability of the McGovern  
12 study.

13 ECRI Institute also notes the confounding and  
14 then, of course, there's the FDA. In 2012, once the  
15 McGovern study came out, Dr. Augustine went on his website.  
16 He's touting it, hey, this is proof that forced air warming  
17 Bair Hugger increases the risk of surgical site infections  
18 and shows the HotDog is safer, and the FDA told him to stop.  
19 They said that the evidence provided in support, which  
20 included the McGovern study, did not "provide conclusive  
21 evidence of a causal relationship between the use of forced  
22 air warming and higher infection rates."

23 This is a preclude, of course, to what they have  
24 now said again recently in response to Augustine's  
25 marketing, advertising around this litigation. And just to

1 go through these confounders, there's no dispute in the  
2 medical literature that these issues that they did not  
3 account for, did not control for in McGovern are  
4 confounders.

5 Here in 1990, Dr. William Jarvis, one of  
6 plaintiffs' experts, while he was at the CDC concluded that  
7 surgical technique in patients, in a patient's severity of  
8 illness were the primary determinate of surgical wound  
9 infection after total knee arthroplasty.

10 We've talked about the fact that when you control  
11 for the two major changes in thromboprophylaxis and  
12 antibiotic that occurred at the very end of the Bair Hugger  
13 period before the transition to HotDog, it wipes out this  
14 association, the purported association.

15 Dr. Holford's biostatistical analysis found the  
16 same thing. He says you can account for all of the  
17 difference in risk reported in the McGovern study simply by  
18 accounting for these two confounding variables. That's  
19 before you get to things like fitness for surgery, obesity,  
20 and so forth. Just those two wipe out any difference.

21 And there's no dispute in the medical literature  
22 that the antibiotic that was used during that tail end of  
23 the Bair Hugger period where you see the spike, Gentamicin  
24 is a less effective antibiotic. Here's Dr. Reed in another  
25 paper, McGovern co-author Dr. Reed says there's no evidence

1 for use of systemic Gentamicin is prophylaxis and primary  
2 elective THA and TKA surgery. And he goes on to say that  
3 they found that staph develops resistance to Gentamicin,  
4 which also can explain the spike.

5 Thromboprophylaxis is also an acknowledged and  
6 recognized confounder. Another change that had been made at  
7 the end of the Bair Hugger period was the use of  
8 Rivaroxaban. And the Brimmo study, which came out just a  
9 couple years ago, 2016, concluded that, "the use of  
10 Rivaroxaban for thromboprophylaxis lead to a significantly  
11 increased incidence of deep SSI," that's what we're talking  
12 about here, deep joint infections, "in a continuous series  
13 of patients undergoing primarily THA and TKA in a single  
14 institution."

15 And I bring us back to McGovern Figure 7. This is  
16 before they flattened out the line using the average. And  
17 what it shows is that there is a peak just before and  
18 infections just before the switch away from Rivaroxaban. It  
19 peaked that the authors then concealed by flattening the  
20 line and using an average. And these were merely elements  
21 of a comprehensive, massive infection control initiative  
22 that was undergoing, that was happening at Wansbeck  
23 Hospital, part of the North Umbria Trust in England at the  
24 tail end of the Bair Hugger period.

25 This is from a study called Gillson. She was the

1 chief nurse who was involved in this initiative. This is in  
2 the record. I don't think we have a cite here. But,  
3 anyway, Figure 2 in the Gillson paper shows all of the  
4 various initiatives that were introduced at the tail end of  
5 the Bair Hugger period and going into the HotDog period.

6 So as Dr. Borak notes, the benefits of this  
7 massive initiative that they had undertaken, multiple  
8 different things was felt primarily by the patients who were  
9 warm with the HotDog, and these include implementing  
10 pre-warming, MMSA screening, changes to operating room  
11 protocols, changing post-operative wound dressings,  
12 repairing the laminar air flow system -- we know that's  
13 important -- undertaking root-cause analysis of infections,  
14 establishing a Prevention Control Committee, hiring  
15 full-time SSI surveillance nurses and implementing more  
16 effective pre-operative skin preparation.

17 Dr. Borak explains why all of these are important  
18 and could well have contributed, likely did contribute, to  
19 the reduction in infections during the HotDog period. All  
20 confounders that in fact are not even disclosed, maybe  
21 obliquely referenced in the McGovern paper, and that's even  
22 before we get to the data manipulation.

23 And as Mr. Corey Gordon demonstrated, and I'll  
24 just do it briefly here, there is a change between draft 10  
25 of the McGovern study and the published version. There is a



1 HotDog infection that disappears and all of a sudden becomes  
2 a Bair Hugger infection. And the data set, which we've  
3 established to be the actual, the real data, is consistent  
4 with the draft and not the published version.

5 And where did this happen? When did this data  
6 switch happen? It happened after Dr. Reed, who sent this  
7 data set to the United States, to Augustine Biomedical and  
8 Design in the possession of Mark Albrecht. And Dr. Reed  
9 testified that there is a difference, a difference between  
10 the data that he sent to Mark Albrecht and the published  
11 data. He agreed with that. He remembered it a little bit  
12 differently from how he showed it in the actual data, but he  
13 knew there was a difference.

14 And so we go from 4 to 3. And that is the  
15 difference between statistical significance and lack of  
16 statistical significance as Dr. Holford shows.

17 In the *Viagra MDL* in this district, the Court  
18 initially had admitted the general causation epidemiology  
19 expert of the plaintiffs, and then after subsequent  
20 discovery revealed that there were serious data credibility  
21 issues with the data set on which the epidemiology expert  
22 relied. The Court reversed course, excluded the expert and  
23 granted summary judgment to the defendants.

24 And Judge Magnuson noted "Peer review and  
25 publication mean little if a study is not based on accurate

1 underlying data." The peer reviewers don't get the data.  
2 They don't get to analyze it. They're presented with the  
3 paper. And the fact that the McGwin study, this was the  
4 single epi study on which the plaintiffs' general causation  
5 expert relied appears to have been based on data that cannot  
6 now be documented or supported renders it inadmissibly  
7 reliable.

8 The data manipulation alone is a sufficient basis  
9 to render the McGovern study unreliable. But even if you  
10 take that out as a factor, the failure to account for  
11 confounders, confounders that explain the entire difference  
12 between the Bair Hugger period and the HotDog period,  
13 renders it as every one of these independent authorities  
14 have found an unreliable basis for making inferences of  
15 causation, and it does it on its face even find an  
16 association.

17 JUDGE LEARY: But even with this alleged  
18 manipulation, the ultimate conclusion remains the same by  
19 Reed and Albrecht that the association is not causal.

20 MR. HULSE: Correct. And that's what the paper  
21 says. As Dr. Reed said, we didn't find an association  
22 between the Bair Hugger system and increased infections.  
23 That's not what we found. And statistical --

24 THE COURT: Just a second. Mr. Sacchet is  
25 indicating that that's not true, I think. So did you want

1 to?

2 MR. HULSE: The Court can read the McGovern study.  
3 I'm confident that they disagree with what I'm saying up  
4 here, but the McGovern study and Dr. Reed's testimony will  
5 speak for themselves.

6 MR. SACCHET: I agree it will speak for itself.

7 MR. HULSE: And statistical significance, as I  
8 showed them, the moving of the single infection removes  
9 statistical significance while statistical significance is  
10 as some court says is not the Holy Grail of admissibility.

11 In the *Prempro* MDL, the Court said, "as many  
12 federal courts observe, if an expert places undue emphasis  
13 on statistically insignificant evidence, it may indicate  
14 that the expert's methods are unreliable." And the Court  
15 cited *Joiner*. In fact, the *Prempro* court did ultimately  
16 exclude general causation experts on that basis.

17 In fact, in *Joiner* itself, *Joiner* involved the  
18 plaintiffs' causation expert's reliance on epi studies. And  
19 despite the existence of epi studies, the Court said the  
20 leaps. This is where that famous ipse dixit language comes  
21 from in *Joiner*. The leaps that were being made by the  
22 plaintiffs' causation experts from these epi studies was too  
23 far.

24 And, again, the last thing on the topic of  
25 statistical significance, we also know because Dr. Holford

1 demonstrates it, the impact of the start date. The study  
2 authors moved the start date to a place where they could  
3 achieve statistical significance. If they had remained with  
4 an earlier date, one month earlier, one month later, they  
5 would have lost statistical significance. The date was  
6 selected to achieve it just barely and that's how fragile  
7 the study is even before you account for confounders.

8 Now, what Dr. Sikka's study published and I showed  
9 earlier, is the significance of the financial interest of  
10 Mr. Albrecht to the trustworthiness of this study. Now, as  
11 we've shown you, Mr. Albrecht had an over \$20,000 promissory  
12 note with Augustine. Of course, he was employed by  
13 Augustine from 2005 onward. He's a long-time employee.  
14 He's the guy who did the data crunching for Augustine, and  
15 he did it for the McGovern study. And I think the  
16 plaintiffs said the day before yesterday, oh, but this all  
17 postdates McGovern. This is a promissory note from 2012.  
18 Well, the first paragraph of this says, "the undersigned is  
19 an addendum to the promissory notes dated September 27,  
20 2007, and August 10, 2010." An addendum to promissory notes  
21 that already existed. Mr. Albrecht owed his employer,  
22 long-time employer, quite a bit of money.

23 But even so, Mr. Albrecht still made clear in a  
24 document and then in his testimony that he didn't support  
25 the inferences that Dr. Augustine was making, the same

1 inferences that the plaintiffs' experts are making here from  
2 the McGovern study:

3 "Unfortunately, Scott likes to say that he's  
4 convinced of such a relationship, that is the relationship  
5 between forced air warming and deep joint infections, even  
6 though I tell him it is unsupported and I do not agree.  
7 Well, that is the difference between research and  
8 marketing."

9 So the Court should not consider the McGovern  
10 study to be scientifically valid evidence of causation upon  
11 which experts can reliably draw inferences of causation.  
12 It's not real world scientists, doctors don't draw that  
13 inference based on McGovern, and they don't draw it based on  
14 McGovern in consideration with the rest of the body of the  
15 medical literature. They don't. The only place they do  
16 that other than in Scott Augustine's marketing is in this  
17 courtroom.

18 We spent a lot of time yesterday on  
19 Dr. Elgobashi's CFD, which is a computer simulation, and  
20 like any simulation is only as good as its inputs. And  
21 general causation has not only the meaning that we've talked  
22 about in terms of whether the Bair Hugger system increases  
23 actually causes deep joint infections, periprosthetic joint  
24 infections.

25 But also general causation involves this question

1 of is this going to be useful in any of the cases, the  
2 4,000-plus cases that we have in the MDL and the 60-plus  
3 that we've got in Ramsey County? And Dr. Elgobashi has got  
4 a temperature input that we have strong reason to believe  
5 that's not the temperature that you'd find if you measured  
6 under the draping in any operating room in America. And so  
7 the relevance of this to any of the cases, the bellwethers,  
8 and so forth that may be tried is dubious.

9 But even beyond that, the plaintiffs don't cite  
10 any case where a CFD has been admitted as proof of causation  
11 of a medical injury. Dr. Elgobashi himself doesn't give the  
12 opinion that general causation can be premised on a CFD. No  
13 other expert in this case has given the opinion that general  
14 causation conclusion can be based solely on a CFD. And the  
15 plaintiffs haven't pointed to any study, and we haven't  
16 found one that says that a CFD can be used to prove the  
17 cause of an infection.

18 And in the plaintiffs' summary judgment  
19 opposition, again, all they say is it's mechanistic  
20 evidence. They don't claim that it can get them over the  
21 hurdle of general causation.

22 Another thing that the plaintiffs' medical experts  
23 rely on is an inference. An inference that increase in  
24 particulate matter in the operating room means you have an  
25 increase in bacteria. So if the Bair Hugger increases

1 particulate matter, then it must also increase bacteria in  
2 the operating room and at the surgical site. That's an  
3 interesting theory, but it's been tested. And as the Court  
4 has heard repeatedly, it's been tested repeatedly.

5 And as Mr. Gordon showed earlier this morning  
6 there are nine studies including most recently Oguz that has  
7 consistently found that the Bair Hugger system does not  
8 increase bacteria. The plaintiffs' theory, while it may  
9 sound facially appealing, is simply not borne out by the  
10 real world evidence. And the plaintiffs' experts Samet,  
11 Jarvis and Stonnington depend on that theory. They depend  
12 on McGovern. They depend on that theory. It's just not  
13 supported by the real world evidence.

14 And the last refuge here, you'll likely hear more  
15 of this from the other side is 3M corporate documents. We  
16 have produced millions and millions of pages of documents in  
17 this litigation. 3M and Arizant's consistent position has  
18 been as is supported by the science that the Bair Hugger  
19 does not increase the risk of infections. What plaintiffs  
20 have done in their brief and may do today is they may pull  
21 out snippets of e-mails, of draft documents, snippets of  
22 deposition testimony that are contradicted as was the case  
23 with Dr. Kurz, by testimony that occurred just pages later  
24 in the deposition.

25 But corporate documents even put in the most

1 favorable light are not proof of causation. A 3M document  
2 could say that an apple is a banana, and it wouldn't make it  
3 a banana. The question is is there scientifically valid  
4 evidence, *Glastetter* standard, scientifically valid  
5 evidence, *Daubert* standard, to support general causation?  
6 Not is there an e-mail or a draft document that we think if  
7 you cut it out and don't look at anything else, could get us  
8 over the general causation hurdle. And courts consistently  
9 have said you can't substitute documents, corporate  
10 documents, for scientific proof.

11 The *Mirena* case out of the Southern District of  
12 New York, which is just affirmed a couple of days ago by the  
13 Second Circuit said, "The statements and public positions of  
14 Bayer are not scientific literature that an expert would be  
15 expected to confront in the exercise of intellectual rigor  
16 in the field."

17 There, we had a situation where actually there  
18 were public statements being made about Bayer that seemed  
19 adverse to their position on general causation. Plaintiffs  
20 won't point to anything like that here.

21 In the *Lipitor* case, there was an alleged  
22 admission in an employee e-mail that Lipitor caused  
23 diabetes, and the Court said, "that could not replace expert  
24 testimony, and it wasn't sufficient to preclude summary  
25 judgment on the issue of general causation."



1           And *Glastetter* too confronted this issue. There  
2       were internal communications among medical professionals, a  
3       defendant, that the plaintiffs suggested with some force  
4       looked like admissions that were contrary to the position of  
5       the defendant that Parlodel did not cause strokes. But the  
6       Eighth Circuit agreed with the District Court that these  
7       purported admissions that were cut and pasted from company  
8       memoranda did not support general causation.

9           You could weave them together with all the other  
10      things that the plaintiffs had in *Glastetter*, things  
11      plaintiffs don't have here: Animal studies, case studies,  
12      rechallenged, dechallenged data. The plaintiffs even had a  
13      medical textbook in *Glastetter* that in the Eighth Circuit's  
14      words ventured a hesitant conclusion that Parlodel caused  
15      strokes. Individually or together, that wasn't sufficient  
16      evidence to get past, to establish the admissibility of the  
17      plaintiffs' general causation experts or to withstand  
18      summary judgment.

19           And then we come to the International Consensus.  
20      General acceptance is a determinative factor under Minnesota  
21      Rule of Evidence 702. And it is a factor to be considered  
22      by the Court under *Daubert*, according to the Advisory  
23      Committee notes to Rule 702. Both sides agree here that the  
24      International Consensus meeting is reliable. These are  
25      people who work and spend their practice on the kind of

1 surgeries that are primarily at issue here in the MDL, the  
2 prosthetic joint infections.

3 And as the Court has heard, the International  
4 Consensus meeting, these 400 professionals, bone doctors and  
5 so forth, reached a strong consensus. And you can look at  
6 their footnotes and they considered the McGovern study.  
7 They considered the mechanistic studies. They considered  
8 the best case for Augustine and the plaintiffs and said, "We  
9 recognize the theoretical risk," theoretical risk, "posed by  
10 forced air warming blankets and that no studies have shown  
11 an increase in SSI related to the use of these devices."

12 Again, they're talking about McGovern, "no studies  
13 have shown an increase in SSI related to to the use of these  
14 devices." They took McGovern's authors on their face and  
15 they said McGovern doesn't show that. "We recommend further  
16 study but no change to current practice."

17 This is the kind of guidance that real doctors,  
18 anesthesiologists, nurses take to heart when they're making  
19 decision about what to do for their patients.

20 They also take to heart what the FDA has to say.  
21 The FDA, of course, responsibilities protecting the public,  
22 protecting patients from unsafe medical devices and  
23 pharmaceuticals. And the FDA just not too many weeks ago in  
24 response as they said to concerns that they were learning  
25 about, about the safety of patient warming and safety of

1 forced air warming in particular issued this letter. And  
2 you can find it on their website along with a series of  
3 other safety-related letters that they issued from time to  
4 time.

5 And what they said is that they considered data  
6 "publicly available medical literature," data from  
7 manufacturers and hospitals, operating room guidelines and  
8 ventilation requirements in assessing whether there was  
9 reason for concern. And their conclusion was this:

10 There are considerable benefits to using patient  
11 warming, including forced air warming in surgeries. And  
12 they didn't make any distinction -- oops, sorry.

13 (Short noise interruption.)

14 MR. HULSE: Mystery solved or remains a mystery?

15 THE COURT: It deepens.

16 MR. HULSE: And the FDA reminded, and this was a  
17 letter addressed to doctors, to health care providers,  
18 doctors, nurses, people who are making decisions about what  
19 to do for their patients:

20 "The FDA is reminding health care providers that  
21 using thermoregulation devices during surgery, including  
22 forced air thermoregulating systems," and the Bair Hugger is  
23 far and away the most prominently used of those, "have been  
24 demonstrated to result in less bleeding, faster recovery  
25 times, and decreased risk of infection for patients."

1           And in fact, the research supports exactly that:  
2       Reduced surgical site infections, reduced fatal heart  
3       attacks, reduced blood transfusions, reduced length of  
4       hospital stay, reduced post-operative shivering. Those are  
5       the benefits of patient warming.

6           But the FDA then goes on to recommend the use of  
7       thermoregulating devices, including forced air  
8       thermoregulating system, like the Bair Hugger, for surgical  
9       procedures when clinically warranted. They don't say except  
10      in orthopedic surgeries, but here's the crux of it. This is  
11      the direction they're giving to health care providers:  
12      "Surgical procedures performed without the use of a  
13      thermoregulation system may cause adverse health  
14      consequences for patients during the post-operative and  
15      recovery process."

16           If you don't warm your patients, you may be  
17      imperiling your health, their health. You are putting them  
18      in danger. And the state of play today is that 70 percent  
19      or more of hospitals are using the Bair Hugger system.

20           So this is the guidance that medical professionals  
21      outside this courtroom taking care of patients performing  
22      surgeries, this is the advice that they've gotten. You're  
23      doing the right thing. Keep doing what you're doing.  
24      You're protecting your patients.

25           And if we go forward based on conclusions drawn in

1 the courtroom by experts who've never drawn those  
2 conclusions outside the courtroom, who claim that studies  
3 say things that they on their face don't say, make leaps  
4 they would -- you can't imagine that they would make in  
5 their professional lives, and it gets to a jury and the jury  
6 is confronted with this and determines, oh, we agree, the  
7 Bair Hugger system is unsafe, what are professionals to do?  
8 The FDA, the International Consensus has told them it's  
9 safe, and now they've got litigation proceedings that say  
10 they're not. They have to make decisions. Now, they're  
11 faced with am I going to be sued for malpractice? They have  
12 to be able to rely on the consensus and what's generally  
13 accepted in the community.

14 What we have here, to return to the original  
15 point, is litigation science, not real science. The  
16 plaintiffs' own studies don't support their causation  
17 theory. And to Mr. Sacchet's point, we encourage the Court  
18 to read the studies. See what they say, not what the  
19 lawyers say about them. Read what they say.

20 The International Consensus, which has read the  
21 studies, the same studies on which the plaintiffs' experts  
22 rely, rejects the plaintiffs' causation theory, and the FDA  
23 rejects it too.

24 Whether it's determinative as in Minnesota or a  
25 factor as under federal law, the consensus rejection of the

1 theory that plaintiffs and their experts have advanced in  
2 this courtroom is powerful evidence of its unreliability.  
3 And plaintiffs have the burden to demonstrate the  
4 admissibility of their expert testimony, and they can't do  
5 it. They don't rely on scientifically valid evidence. They  
6 make flying leaps across the chasm from plausibility and  
7 theory to causation, which under *Joiner* they can't do.

8 We ask the Court to exclude the plaintiffs'  
9 medical experts, grant summary judgment in the cases in the  
10 MDL and in Minnesota. Thank you very much.

11 THE COURT: Thank you, Mr. Hulse. Ms. Conlin.

12 MS. CONLIN: Good afternoon, Your Honors. While  
13 that's getting set up, I just want to circle back briefly to  
14 the August 2017 FDA letter and that's the letter that just  
15 came out in August of this year. We immediately saw it,  
16 knew that it wasn't a letter that the FDA typically issues,  
17 and we proffered discovery on 3M on this. We were stone  
18 walled on that. They said we're not going to give you  
19 discovery. It is not relevant to the claims and defenses in  
20 this case, and discovery is closed.

21 We learned for the first time at the first day of  
22 this hearing under questions, direct questions from this  
23 bench to Mr. Blackwell that in fact 3M was behind that  
24 letter. And we don't know what their communications were.  
25 We don't know what the FDA looked at, but Mr. Blackwell

1 readily conceded 3M asked the FDA to investigate the claims  
2 that Scott Augustine was making in the science.

3 We're not representing Scott Augustine in this  
4 case as in Augustine v. 3M. It's plaintiffs. But for some  
5 reason, just because we are making and have proven the same  
6 claims that perhaps Mr. Augustine is making, we've been  
7 tainted with that. And as Mr. Ciresi said, we're looking  
8 forward to having him on cross-examination.

9 THE COURT: Ms. Conlin, anything you want to say  
10 on the summary judgment?

11 MS. CONLIN: I do. And he raised that letter in  
12 the summary judgment, so I just wanted to address that  
13 first.

14 I want to start with the notion of what is  
15 actually in dispute in connection with this motion. 3M  
16 doesn't dispute the qualifications of Dr. Samet, Dr. Jarvis  
17 or Dr. Stonnington. There is no dispute that these are  
18 eminently qualified, and in the case of Dr. Jarvis and  
19 Dr. Samet world renowned in their respective fields.

20 3M doesn't dispute the methodology that those  
21 experts employ. Dr. Samet employed the Bradford-Hill  
22 criteria. There's no argument by 3M that he didn't  
23 faithfully and systematically apply those criteria. And  
24 really what it boils down to, the main thrust of this entire  
25 hearing has been 3M's criticism of McGovern, which is a

1 single piece of evidence amongst the body of things that,  
2 for example, Dr. Samet looked at.

3 And when we were talking about Dr. Samet, I went  
4 through that, and there was literally hundreds and hundreds  
5 of references and lines that he went through in making his  
6 causation determination. Things which didn't exist at the  
7 time of the 2013 consensus, such as the heater-cooler issue,  
8 such as Darouiche.

9 And, most importantly, Dr. Elgobashi's CFD  
10 modelling, which 3M knows is good science, which is why we  
11 spent half a day yesterday arguing about whether his input  
12 was correct, when in fact both experts, Professor Abraham  
13 and Dr. Elgobashi both used the same temperature input for  
14 the purposes of their model. There's no dispute here.

15 3M says that basically so long, and this is a  
16 quote from their brief, Your Honors, "so long as the Court  
17 excludes plaintiffs' three medical experts, summary judgment  
18 is appropriate." And I want to talk a little bit about that  
19 because, again, really the focus has been on McGovern.

20 But some of the third party research relied upon  
21 by the experts show that Bair Hugger increases particles  
22 over the surgical site. 3M's 30(b)(6) witness Al Van Duren  
23 testified under oath every single study that is out there  
24 indicates that the Bair Hugger increases particle count over  
25 the sterile field. The Legg and Sessler studies the same.



1           There is evidence and scientific studies showing  
2           that the Bair Hugger increases bacteria over the surgical  
3           site. The Moretti, Wood and Tumia references that are in  
4           our papers. And the relationship of particles and bacteria  
5           to infection, and the Darouiche study, which we have cited  
6           in our papers as well and talked about over the course of  
7           the last couple of days.

8           Doubts under the Eighth Circuit as well as the  
9           Frye standard are resolved in favor of admissibility. The  
10          Court abuses its discretion if it results Doubts in favor of  
11          excluding expert testimony or decides the correctness of the  
12          expert opinion.

13          And in fact this morning, you heard Mr. Hulse  
14          accuse the McGovern authors of data manipulation, of  
15          changing Figure 7. Well, we intend to subpoena Mr. Albrecht  
16          and Professor Nachtsheim from the University of Minnesota  
17          School of Management, and those questions can be posed to  
18          him why was the change done and the averaging done in that  
19          study, because that's what they're accusing.

20          They're accusing Dr. Belani, who is head of  
21          anesthesiology at the University of Minnesota of academic  
22          fraud. And those are serious allegations, but they also go  
23          to credibility and not the study itself.

24          We've never misrepresented McGovern. What we've  
25          said is it shows a strong association between Bair Hugger

1 and deep joint infection, and that's all we've ever cited it  
2 for. We have been very clear since day one that study  
3 doesn't show causation. It shows an association, which is  
4 why the experts relied on scores of other literature,  
5 including the depositions of 3M in this case, including the  
6 Dr. Elgobashi model, including the Darouiche study, that was  
7 that entire cumulative body of evidence that led to the  
8 causal connection that our experts have opined on.

9 And 3M, by the way, doesn't have a single, not one  
10 epidemiological study which disproves what the McGovern  
11 authors found. Not only do they not have any evidence on  
12 that, but they've refused to do it despite the urging of the  
13 people affiliated both on their external advisory panel as  
14 well as internal people.

15 We've talked about this, but epidemiologic studies  
16 show associations. They do not prove causation, and we have  
17 been upfront and candid and clear on that. The evaluating  
18 causation requires scientific judgment and expertise.  
19 That's the job of an epidemiologist.

20 We have one here who methodically, you didn't hear  
21 him saying that Dr. Samet didn't go through the entire body.  
22 If you look at his report on page 2 or 3 it might be, where  
23 he goes through and lists the searches that he did. He  
24 actually put in his report these are the literature searches  
25 I did in connection with that. And beyond that listed some

1 200 different lines of evidence in connection with his  
2 opinion. And what he did and what hasn't been done to date  
3 is that he connected all the dots and that's often what  
4 cases like this turn on is having somebody who takes the  
5 time to sit down and connect all the dots.

6 The Court said it, I don't need to say it again.  
7 Opposing experts often interpret the same studies  
8 differently. That's what cross-examination is for.

9 Now, Dr. McGovern is one of the authors that 3M  
10 has accused of data manipulation. He was deposed --

11 JUDGE LEARY: Let me comment on that statement,  
12 Ms. Conlin.

13 MS. CONLIN: Sure.

14 JUDGE LEARY: I don't hear the defense saying that  
15 these authors all participated in a manipulation of the  
16 data. The way I understand the argument based on the  
17 evidence that's been produced is that a change occurred when  
18 after draft 7 when the information was placed in the hands  
19 of Mark Albrecht, and that Mark Albrecht was responsible for  
20 the data and the representation of the data and the article.

21 Now, maybe I misrecall that, but to the point of  
22 you're saying that the defendants are claiming that all of  
23 the authors engaged in scientific fraud, I haven't heard  
24 that from them; maybe I misunderstand the evidence, but I  
25 haven't heard that characterization.

1 MS. CONLIN: Well, I think that it has been stated  
2 most recently in connection with Mr. Hulse's summary  
3 judgment motion. I can pull the transcript but that --

4 JUDGE LEARY: What I heard him say attributed the  
5 alleged manipulation to Mr. Albrecht, to no one else.

6 MS. CONLIN: Okay. And maybe I extrapolated  
7 beyond what he said. I guess the record will speak for  
8 itself. Mr. Albrecht and, again, that is a credibility  
9 issue, but there is no foundation for what 3M has said about  
10 the data manipulation.

11 THE COURT: Just hold on one second. I'm  
12 scratching around in my memory. Was it -- did Mr. Albrecht  
13 send a prior version of Figure 7 to Dr. Augustine with the  
14 statement, "we've reached statistical significance." And  
15 then following a response from Dr. Augustine, did the data  
16 change? Is that what --

17 MS. CONLIN: No, that is not. And the e-mail that  
18 you're referencing, I know somebody is probably pulling it  
19 up for me. But if you look at the next e-mail below it,  
20 it's from Dr. Reed. And what he says is, yeah, we knew that  
21 we would reach statistical significance because they  
22 believed in that and that it was only a matter of time.

23 THE COURT: So Augustine was not in that at all.

24 MS. CONLIN: He might have been copied. My  
25 understanding is he was copied on a lot of that.

1 THE COURT: I think you're getting the facts right  
2 now.

3 MR. CIRESI: If I may approach, Your Honor, to  
4 give the e-mail itself.

5 MS. CONLIN: Go ahead.

6 MR. CIRESI: And, well, I'd have to ask leave of  
7 the Court to argue this, but this goes directly to what  
8 Judge Leary --

9 THE COURT: I just want -- Ms. Conlin, is this --

10 MR. CIRESI: Yes, this is the document.

11 THE COURT: Who is it too and from on that?

12 MS. CONLIN: It's an e-mail from Mark Albrecht to  
13 Drs. Reed, McGovern, a CC to Scott Augustine and Christopher  
14 Nachtsheim at the University of Minnesota. It says, "Gents,  
15 attached is an updated chart of infection data. The  
16 difference is significant based upon the results of logistic  
17 regression."

18 It goes on to say some highlights. And it says,  
19 "okay, we made it to significant difference, so I'll update  
20 the manuscript to reflect the new infection numbers. I'll  
21 also dig into the difference between hip and knee data and  
22 get back to you on that."

23 That's what Mr. Albrecht was is he was the  
24 statistician who was crunching the numbers that were being  
25 given him by Dr. Reed. Dr. Reed was the one. Now, Dr. Reed

1       probably has the final data set, which is reflected in the  
2       McGovern report. We couldn't subpoena documents from  
3       Dr. Reed because of the --

4               THE COURT: Because of the English thing.

5               MS. CONLIN: The English thing. So this entire  
6       Mark Albrecht said when he was showing it in his deposition,  
7       he said, "I don't know if this is the final data set or not  
8       because it resided with Mr. Reed."

9               But the idea, and to be honest, I mean to be  
10      totally candid with the Court, Dr. Reed did testify in his  
11      deposition, and it's five years after the studies, he said,  
12      "I recall there being one more infection in each group," but  
13      he wasn't entirely sure. Okay. If you're going to cook the  
14      books, you're not going to move one infection.

15              And in fact Professor Holford, if you look at his  
16      report in his very first footnote, he says, "if there's one  
17      more infection in each group, it drops the odds risk ratio  
18      from 3.8 to 2.86. So it doesn't drop it below statistical  
19      significance even if Dr. Reed's post-recollection belief of  
20      the final numbers was accurate, but we don't -- no one has  
21      the final data set. It hasn't been produced.

22              THE COURT: But it's not -- did Reed recall that  
23      there was one more in each group or that there was, I think  
24      that was his recollection. But I think what the defendants  
25      are saying -- obviously, we're going to have to go dig this

1 up -- that one moved, so it's not two more, one for each  
2 side. It's minus 1 for HotDog or minus 1 for Bair Hugger  
3 and plus 1 for HotDog, right?

4 MS. CONLIN: Right. Dr. Reed didn't testify to  
5 that.

6 THE COURT: 2.8 is plus one for each side, right?

7 MS. CONLIN: Yes. But the entire crux of their  
8 argument is based on this Albrecht Exhibit 10, which even  
9 Mark Albrecht said I don't know if that's the final data.  
10 And part of that was because the authors continued to study  
11 post the McGovern study, so they were updating with new  
12 figures all the time.

13 But even if, even under their theory that somehow  
14 magically they had foundation to say that Exhibit 10 out of  
15 Albrecht is the final data set for McGovern, which nobody  
16 has testified to, even under their theory, unless you go to  
17 the chi-square versus Fisher exact, you're still in every  
18 single scenario over statistical significance.

19 And I think one of the things that and, you know,  
20 Dr. Reed said he's the one who kept the data. And he very  
21 clearly said I stand behind this study. And he in fact went  
22 and did further research on the identified potential  
23 confounders in the McGovern study, the anti-thrombo regimen  
24 and the change in antibiotic regimen.

25 And he said in connection with his further study,

1 he concluded that neither one of those were confounders in  
2 McGovern, and they haven't cited anything, any medical  
3 literature or anything to suggest that either one of those  
4 two were actual real confounders. And it's very, on  
5 observational studies, I'm going to show you a few examples  
6 including the ones 3M is relying on, the researchers always  
7 says there's potential confounders.

8 THE COURT: Does The Scientific Manual, Mr. Hulse  
9 put some words up from that this morning, does it say when  
10 you're relying on observational studies, you should have  
11 more than one?

12 MS. CONLIN: Well, one of the Bradford-Hill  
13 criteria, Your Honor, is that you have some consistency  
14 amongst the literature that you're looking at. And in fact,  
15 Dr. Samet went through that in great detail about looking at  
16 the other studies and saying these are consistent. They  
17 don't have an odds risk show because it wasn't a randomized  
18 trial, but these studies are consistent with the conclusions  
19 drawn in McGovern.

20 THE COURT: Other observational studies.

21 MS. CONLIN: Yes. So Dr. Reed says under oath he  
22 stands behind it. And to make sure I was being clear with  
23 the Court, you can see at the bottom, he says, "so what we  
24 have shown is an association not causation. We made that  
25 very clear in the paper."



1           3M has hired the McGovern co-authors. They've  
2           never gone to Dr. Reed and say we think that this is -- I  
3           mean and think about it. I mean Dr. Reed does work for 3M.  
4           Do you think that under any conceivable scenario, if he  
5           thought that this study was not valid that he would stand  
6           behind it?

7           3M, I mean here's an e-mail from Mr. Blackwell to  
8           Judge Noel regarding these UK depositions on September 19th  
9           of last year. And he says, "Drs. Harper and Reed are  
10          prominent researchers in the UK and both have received  
11          funding from 3M for important research activities over the  
12          years. Indeed, Dr. Reed is currently involved in unrelated  
13          research project for another group at 3M."

14          The fact that somebody sponsors or funds a study  
15          does not mean that the study is not valid. It happens all  
16          the time. And I'm going to show you some examples. But  
17          they think enough of Dr. Reed that they've been using him  
18          for other work for him and yet, Dr. Reed has never said I  
19          don't stand behind McGovern. He said exactly the opposite.

20          Dr. Belani at his deposition on page 220, lines 22  
21          through 221, line 2:

22          "Okay, do you stand behind the protocols and work  
23          which resulted in the Belani Deposition Exhibits 4, 5 and  
24          6?" Which are the Belani, Albrecht and McGovern studies  
25          respectively. He says, "I do."

1 Same with Professor Nachtsheim, and you'll be able  
2 to ask him why did you do the flattening out of the graph?  
3 Why was the flattening, the average done? It's done all the  
4 time in regression analysis.

5 He says, "Question: Do you continue to stand by  
6 the results of the observational studies?"

7 "Yes."

8 "In the McGovern publication?"

9 "I do."

10 THE COURT: What are the other observational  
11 studies comparing Bair Hugger with HotDog?

12 MS. CONLIN: McGovern is the only one comparing  
13 the two from an infection standpoint.

14 THE COURT: Okay.

15 MS. CONLIN: There are other studies that show  
16 particulate and bacteria and the other things that the  
17 experts have relied on.

18 THE COURT: Because that was the plurals, the  
19 observations.

20 MS. CONLIN: Yeah, right. And Mr. Albrecht, which  
21 again both Your Honors touched upon it, so I think it's  
22 important to pause here about, well, maybe he was the one  
23 who did this purported unfounded and no evidence supported  
24 data manipulation.

25 And what's interesting is they keep going to an

1 internal e-mail by Mr. Albrecht. And what Mr. Albrecht said  
2 in that e-mail was Scott Augustine is going too far with the  
3 McGovern study, so rather than being somebody who was just  
4 following whatever Scott Augustine said. You saw the  
5 internal document, 3M is relying on it, where Mark Albrecht  
6 says he's taken this too far. All the study showed was  
7 association. He can't say that study alone proves  
8 infections.

9 THE COURT: I thought that e-mail -- I thought the  
10 e-mail said -- I don't know if it was an e-mail, you know  
11 the screen that was up this morning or this afternoon, not  
12 very long ago, I should remember.

13 MS. CONLIN: Yeah.

14 THE COURT: Albrecht was saying Augustine wants to  
15 go farther and show that there is causation. Is that what  
16 he said? Or did he say he wants to show that there's --

17 MS. CONLIN: What he said was, you know, and I'm  
18 paraphrasing because I don't have it here. But, basically,  
19 that Augustine was using McGovern and trying to market it as  
20 proof that the Bair Hugger causes infection. And as we've  
21 seen, all the study authors only said it showed an  
22 association.

23 THE COURT: But that's going to say it says  
24 causation not association, right?

25 MS. CONLIN: Yes, proof, I think it said proof of

1 infection.

2 MR. CIRESI: Your Honor, may I approach? I have  
3 it.

4 THE COURT: Oh, thank you.

5 MS. CONLIN: Thank you, Mr. Ciresi. Here's the  
6 quote, this is from 3M's brief at page 16:

7 "In a communication with another researcher,  
8 Albrecht admitted that he had admonished Augustine  
9 apparently to no effect not to overstate the studies  
10 findings. This is one of those things where we can step  
11 close to the line, and we do have important information to  
12 present that clinicians should be aware of. But we also  
13 have to be careful that we do not state claims regarding  
14 proof of infection reduction. Unfortunately, Scott  
15 Augustine likes to say that he's convinced of such a  
16 relationship even though I tell him it is unsupported, and I  
17 do not agree."

18 THE COURT: So his relationship, he didn't say  
19 association, and he doesn't say cause, he says  
20 "relationship."

21 MS. CONLIN: Yeah, association.

22 THE COURT: He says 'relationship.' He doesn't  
23 say "association," right?

24 MS. CONLIN: Yes, I mean, yes. It says,  
25 "relationship." But what he testified to --

1 THE COURT: Or is it regarding proof? Okay, so  
2 proof, and then such a relationship refers back to proof, I  
3 suppose, as a grammatical matter.

4 MS. CONLIN: Yeah, and it says, "unfortunately,  
5 Scott Augustine likes to say he's convinced of such  
6 relationship even though I tell him it is unsupported and I  
7 do not agree." And in fact consistent with that in his  
8 deposition, he testified, "Do you agree with the  
9 characterization that you're study found forced air warming  
10 found 3.8 times increase in deep point infection rates?"  
11 Here's what Mr. Albrecht said: "I would agree that it's  
12 associated with the 3.8 times increase, that's what the  
13 study would say."

14 So even the individual that they're accusing of  
15 manipulating this has testified very truthfully and in fact  
16 pushed back on the internal statements by Augustine.

17 We've talked about the tabulation error, and under  
18 the alleged tabulation error, and under any scenario, the  
19 study still has statistical significance. And, again, 3M  
20 hasn't posited any foundation for that notion that Albrecht  
21 10 is the final data set. It just doesn't exist.

22 The hypothetical confounders, you saw the  
23 testimony from Dr. Reed that they investigated those  
24 confounders and found that they in fact did not confound the  
25 study. And with respect to the fabricated start date,

1       there's been absolutely nothing other than lawyer argument  
2       regarding the start date.

3               Dr. Reed, the same individual who 3M has hired  
4       time and time again to do study for them says that he picked  
5       the start date of July 1, 2008, because he felt like that  
6       was the first time where full-time surveillance for  
7       infection rates at these three hospitals occurred. There's  
8       no evidence for that. And as we've been beating a dead  
9       horse at this point, but those challenges go to the weight  
10      of the testimony on McGovern, not its admissibility.

11             On the confounders, we showed you the other day  
12      Dr. Reed's testimony. Here's a quote from 3M's expert  
13      Professor Holford: "Question, so there's no published  
14      literature that you're aware of that suggest a relationship  
15      between the variable of thromboprophylaxis on the outcome of  
16      deep joint infection?"

17             "I don't have any."

18             And the Brimmo, by the way, because they brought  
19      up Brimmo study today, there isn't a single one of 3M's  
20      experts who have even cited Brimmo. No one is relying on  
21      the study that they're not putting in front of the Court to  
22      say that it's a problem.

23             A change from gentamicin to gentamicin plus  
24      teicoplanin. Again, absolutely no scientific literature to  
25      support that. And Professor Nachtsheim said he concluded

1 and was confident that the antibiotics weren't confounding  
2 factors. Same thing that Dr. Reed testified to. And on the  
3 SSI bundle protocol that you saw this morning, basically,  
4 their expert said we have no idea. We're just  
5 hypothesizing. So that's not a confounder.

6 Peer reviewed articles are generally reliable.  
7 *Daubert* says that. Peer reviewed, of course, isn't the  
8 end-all, but it certainly is an important characteristic or  
9 indicia of credibleness with respect to a study.

10 One of the things that Judge Leary, you asked  
11 about, well, wasn't there funding by Augustine? Didn't he  
12 supply the blankets and do some of that? And so, frankly,  
13 we looked for cases on this, but most of the studies that  
14 are out there are funded by someone, so it was hard to find  
15 cases on it. These are two that we found. And in fact,  
16 unlike McGovern, I mean, yeah, unlike McGovern, in the  
17 *Burton* case, there were studies that had been funded for the  
18 purposes of litigation. That wasn't enough. It was  
19 insufficient to undermine the reliability of plaintiffs  
20 expert opinion to the point of rendering it inadmissible.

21 JUDGE LEARY: Just for the sake of the record that  
22 will be developed on, I don't remember him making any  
23 statement about Augustine providing blankets or anything  
24 like that.

25 MS. CONLIN: Oh, no, I was saying that because my

1 understanding is he did, Your Honor. I was not attributing  
2 that to you, and I apologize if that was the inference.

3 Here's the Sessler study, which is interesting  
4 because 3M relies on this study to say the Bair Hugger is  
5 safe. A couple of interesting things about the Sessler  
6 study, and they've been putting it up on their slide.

7 The authors thank Gary Hansen of Arizant for  
8 providing not only content resources but editorial  
9 assistance. And if you look in the disclosures there, it's  
10 got Russell Olmsted, contribution, conflicts. He consulted  
11 for Arizant Health Care. So, again, a connection there that  
12 is on the same study that 3M is, you know, relying on to say  
13 that the Bair Hugger is safe.

14 What's also interesting about this is, this is the  
15 study that 3M relies on to say the Bair Hugger is safe, and  
16 I mean they cite other stuff, but in their marketing  
17 literature and the like the Sessler study looms very  
18 prominently in their rebuttal to our case.

19 THE COURT: Is that --

20 MS. CONLIN: It's actually Exhibit 4.

21 THE COURT: Does it have another name?

22 MS. CONLIN: We refer to it as the Sessler study,  
23 Your Honor. It is Exhibit 4 to our brief in opposition.

24 THE COURT: Okay.

25 MS. CONLIN: And what's interesting about this



1 study is that 3M relies on it trying to say that this shows  
2 that the Bair Hugger is safe. You know what they were  
3 measuring in this study? They were measuring particles, the  
4 very thing that they now stand up and say particles can't be  
5 a proxy. Well, this was a study that looked at particles.

6 THE COURT: I suppose it depends on -- I mean if  
7 you don't get any particles, it doesn't matter if they're a  
8 proxy, but if you do get particles, then it matters if  
9 they're a proxy.

10 MS. CONLIN: Yeah.

11 THE COURT: Maybe they said there aren't any  
12 particles.

13 MS. CONLIN: Well, no. Actually, what Dr. Sessler  
14 testified to in his deposition was that there was a ten- to  
15 twelve-fold increase in particles over the surgical site in  
16 this study when the Bair Hugger was on, and we've cited to  
17 that testimony, ten to twelve times more particles when it  
18 was on.

19 The Kurz study from 1996, this is the only study  
20 that exists that says warming of patient during surgery  
21 reduces surgical site infections, the only study that 3M has  
22 ever relied on. It was funded by Augustine when he used to  
23 own the Bair Hugger company, and what's interesting is, this  
24 is study. We showed you the testimony that both Dr. Kurz  
25 and Dr. Sessler now disavow. This is a study that's been

1       disavowed at least in depositions by the study experts.

2               And what's also interesting about this, a quote of  
3       out of here where they talk about confounders in the  
4       studies, which is very similar to the type of language that  
5       you saw in McGovern and is very, very routine with  
6       observational studies, but Dr. Kurz and Dr. Sessler say  
7       other factors may have influenced in the patient's  
8       susceptibility to wound infection, and they go on from  
9       there.

10              THE COURT: Does the Sessler, is the 10 to  
11       12 percent, is that in what size particles?

12              MS. CONLIN: I don't think they were measuring. I  
13       would have to double check, Your Honor. I don't believe  
14       they were saying what the size was. I may be mistaken on  
15       that. I'm not entirely sure.

16              And in fact, Dr. Kurz said, you know, in response  
17       to a question, In today's scientific standards there's no  
18       reliable evidence that supports maintaining normothermia  
19       reduces the incidence of an infection? She said, That is  
20       correct.

21              So I'm going to have, Ms. Zimmerman is going to  
22       talk about the specific studies because one of the things  
23       that 3M has argued is that, that if Samet, Jarvis and  
24       Stonnington goes, our case goes, and we think if Samet,  
25       Jarvis and Stonnington stay in, that's the end of the

1 inquiry, but we don't think the converse is true for reasons  
2 that Ms. Zimmerman is prepared to talk about.

3 THE COURT: Great.

4 MS. CONLIN: Thank you.

5 THE COURT: Thank you very much, Ms. Conlin.

6 MS. ZIMMERMAN: And as we approach the studies --  
7 May it please the Court, Counsel:

8 THE COURT: Welcome back.

9 MS. ZIMMERMAN: Thank you. As we approach the  
10 studies, we're going to go back through the mechanism of  
11 injury here, the mechanism of defect that has been  
12 established through the plaintiff's evidence.

13 And I point the court to a statement that was made  
14 by Mr. Goss yesterday as we were talking about the  
15 106 degrees that was used by Dr. Elgobashi and of course by  
16 Dr. Abraham as well, but Mr. Goss conceded appropriately  
17 that really these are issues that go to the weight, not to  
18 the admissibility.

19 Now, we have different arguments with respect to  
20 Dr. Abraham that I will not go back over for the Court, but  
21 much of the evidence and much of the argument that has been  
22 presented to Your Honors over the past nearly three days now  
23 goes to interpretations about studies, about depositions  
24 about scientific principles.

25 So let's walk through what the plaintiff's proof

1 is in this case. Plaintiff's proofs are grounded in  
2 well-accepted methods. Science has established that  
3 bacteria can cause periprosthetic joint infection. Science  
4 has established that computational fluid dynamics is a  
5 reliable and accepted tool to test operating room particle  
6 movement.

7 That's what Dr. Memarzadeh did. In fact,  
8 Dr. Memarzadeh used 108 degrees, by the way. He modelled  
9 particles in a CFD. He used a less sophisticated model. He  
10 used the RANS model instead of an LES, but that's what the  
11 gold standard has been up to now, and that's really the  
12 basis for the ASHRAE standards on operating room error.

13 Science has established that particles are a  
14 reliable and accepted proxy for bacteria. Science has  
15 established that blowers in the operating room create  
16 additional risk, and we'll talk about that in connection  
17 with the heater-cooler. Well rounded, established and  
18 generally accepted scientific methodologies and principles  
19 form the basis of every expert opinion offer by plaintiff's  
20 experts in this case.

21 The Court is well aware of the standards with  
22 respect to summary judgment, and I wanted to touch on a  
23 question that Judge Leary asked the other day about the  
24 applicability of *Gold v. Tharaldson* to this matter. So *Gold*  
25 *v. Tharaldson* is the Minnesota Supreme Court case where

1 Minnesota declined to adopt *Daubert*, but rather than move to  
2 *Daubert*, what happened was, the Minnesota Supreme Court said  
3 we're going to stay with our normal two-prong test.

4 And that is that the evidence has to be generally  
5 accepted, relevant in the scientific community, and it has  
6 to be foundationally reliable, but the question, and I think  
7 it's been conflated by counsel for 3M in the briefing in  
8 particular, they suggest that the standard in Minnesota is  
9 that the opinions need to be generally accepted, and that is  
10 absolutely not the standard in Minnesota or in the federal  
11 courts.

12 Now, we've cited a Texas case, *Burton versus*  
13 *Wyeth*, which is 2007 from the Northern District of Texas,  
14 and I would point the Court to this language: So it says,  
15 When determining the admissibility of expert testimony, the  
16 trial court is not to consider the conclusions generated by  
17 the expert witness, but only the principles and  
18 methodologies used to reach those conclusions.

19 When the principles and methodology are sufficient  
20 to allow an expert opinion to be presented to the jury, then  
21 the party challenging that testimony must resort to vigorous  
22 cross-examination, presentation of contrary evidence, and  
23 careful instruction on the burden of proof.

24 THE COURT: What's the case?

25 MS. ZIMMERMAN: Yes, Your Honor. It is *Burton*

1        *versus Wyeth*, and it is 513 Fed.Supp.2d 719. That's the  
2        Northern District of Texas in 2007, and the reason that this  
3        was an interesting case was that the Court was really  
4        interesting again a pharmaceutical product that the  
5        plaintiffs alleged it was a Fen-Phen, I believe, and they  
6        were alleging some sort of a heart problem.

7                Again, it's different from this case because we  
8        don't have -- in this *Burton* case, there was a question  
9        about can that drug cause the kind of problems, and here we  
10       know that bacteria can cause the problems the plaintiffs  
11       have alleged, but again the Court noted at, it's star 726  
12       the fact that in that instance, the defendant was not  
13       challenging the validity of the -- the challenge was to the  
14       conclusions, not to the methodology.

15               And the way that they tried to do that was by  
16       offering competing studies, and the Court properly  
17       determined that that is not what is supposed to be done at  
18       the *Daubert* stage in determining whether or not expert  
19       testimony can be properly presented to the trier of fact.

20               We entered some cases in the record yesterday and  
21       comments to Rule 702 on point as well. This is an issue for  
22       the trier of fact, but just to be clear for the Court, the  
23       methodologies that are at use by Dr. Elgobashi are certainly  
24       well accepted. He did not invent CFD. They're routinely  
25       admitted in courts that follow either *Daubert* or the *Frye*

1 standard.

2 The Bradford Hill criteria are routinely admitted.  
3 The methodologies, and again Ms. Conlin pointed to this.  
4 There had been not been an attack on the methodologies  
5 employed by the plaintiff's experts. The attacks repeated  
6 over the past few days have been on McGovern, but McGovern  
7 is published. It is peer reviewed, and it is appropriately  
8 part of what plaintiff's experts rely upon.

9 So let's talk about what it is that 3M knew and  
10 when did they know it and what did they do about it. So  
11 airborne contamination, that's a risk that 3M has known for  
12 certainly over 20 years. This is the 510K submission that  
13 was submitted to the FDA, and I offer this only so that Your  
14 Honors are reminded that even back in 1996, under number one  
15 contamination:

16 Airborne contamination from airborne  
17 intraoperatively across the surgical wound may result in  
18 airborne contamination. The notion that bacteria that can  
19 cause infections might become aerosolized and travel through  
20 the air was known certainly by 1996, and as we presented to  
21 the Court in our papers and in prior argument, it was even  
22 warned about on the original device that was not used in an  
23 operating room.

24 Another piece of evidence that we touched on a  
25 little bit yesterday that was not before the international

1 consensus committee prior was the heater-cooler situation,  
2 and so what I do is ask that Your Honors pay particular  
3 attention to Exhibit 45 to our motion, and this is the CDC  
4 health care infection control practices advisory committee  
5 notes, and particularly on page 27, the CDC concludes, and  
6 this is in 2015, nothing that blows air should be in an  
7 operating room theater if possible.

8 That's because of the studies that were done in  
9 the heater-cooler where they understood perhaps for the  
10 first time as concretely that this particular kind of  
11 bacteria, any bacteria could be aerosolized, travel through  
12 the air and cause an infection, and so the CDC did an  
13 investigation, and this ultimately lead both to the recall  
14 of the Sorin 3T cooler devices and to this warning about  
15 blown air in an operating room.

16 JUDGE LEARY: Could you go back to that?

17 MS. ZIMMERMAN: Certainly. And this is Exhibit  
18 Number 45, Your Honor.

19 JUDGE LEARY: It says, The heater-cooler unit,  
20 first line, appears to be harmless.

21 MS. ZIMMERMAN: It does.

22 JUDGE LEARY: From an infection perspective, but  
23 the water overflow bottle is likely rarely, if ever,  
24 sanitized and is situated in front of a fan.

25 MS. ZIMMERMAN: That's right, Your Honor.



1 JUDGE LEARY: Am I wrong in interpreting that  
2 sentence as saying the problem is not with the heater-cooler  
3 unit but with the water overflow bottle?

4 MS. ZIMMERMAN: Respectfully, no, Your Honor.  
5 The issue that the CDC pointed to was actually looking at  
6 this machine at first glance, these are machines that have  
7 been used in an operating room for decades, particularly  
8 with respect to heart surgeries, and no one prior to these  
9 surgeries had ever considered that that particular device  
10 might be capable of both hosting pathogens, and then by  
11 blowing the air out of that machine, there's an exhaust fan  
12 on the machine, that blowing the air might result in  
13 aerosolization of that bacteria and transport to the  
14 surgical site.

15 THE COURT: What's this CDC publication about? Is  
16 it about air, or is it about this heater-cooler unit?

17 MS. ZIMMERMAN: It is about the heater-cooler  
18 unit.

19 THE COURT: So these are comments that are made as  
20 an aside as dicta while they're talking the dangers of the  
21 heater-cooler unit.

22 MS. ZIMMERMAN: Yes, Your Honor. That is true.

23 THE COURT: But don't put a bucket of never  
24 cleaned infected water in the operating room.

25 MS. ZIMMERMAN: Well, I think that's part of it

1 and that that water inside the heater-cooler was a  
2 particularly hospitable place for the bacteria to grow.

3 THE COURT: It condenses, and it changes  
4 temperature, and it drips, and it causes --

5 MS. ZIMMERMAN: It does, and the Mycobacterium  
6 chimaera, the kind of bacteria that was there, is very slow  
7 growing bacteria that likes water, but as in this case, the  
8 Bair Hugger is a very hospitable environment.

9 THE COURT: Is there a similar statement that says  
10 Bair Hugger is a hospitable environment, just as there is  
11 the heater-cooler thing is a hospitable environment?

12 MS. ZIMMERMAN: There hasn't been a comparison  
13 between heater-cooler in that way, but there is admissions  
14 from defense counsel and from corporate witnesses that these  
15 devices do indeed harbor bacteria.

16 THE COURT: Right. We've got the swabbing and  
17 everything. The statement that's similar to the  
18 heater-cooler that was examined by the CDC, the Bair Hugger  
19 is a particularly hospitable environment for bacteria?

20 MS. ZIMMERMAN: Some of that testing was done in  
21 connection with Project Ducky, I believe, and an evaluation  
22 about whether or not it would be appropriate to line the  
23 inside of a hose, for example, with a kind of a silver  
24 nitrate that might make the hose less susceptible or less  
25 hospitable to these kinds of pathogens.

1 THE COURT: Project Ducky is a new one on me.

2 MS. ZIMMERMAN: I don't think that Project Ducky,  
3 in full disclosure to the Court, is attached to the papers  
4 that we've presented here. They were attached to our  
5 punitive damages motion. So it's part of the record, and  
6 I'd be glad to get the citation for Your Honors.

7 But again, the reason that this is important is,  
8 we want to understand that these kinds of devices that are  
9 in the operating room, they can host bacteria. That  
10 bacteria can become aerosolized because of blown air, which  
11 certainly happens with the Bair Hugger. That's what it's  
12 there to do, and the air can carry these bacteria into the  
13 surgical site, and Dr. Elgobashi's analysis explains in  
14 greater detail how that might happen.

15 Again, the Court, both of you, have heard much  
16 argument and evidence over the past several of days about  
17 what we agree about. We all know that bacteria is what  
18 causes these periprosthetic joint infections. The  
19 inoculation, the dose of bacteria when you're talking about  
20 a deep joint infection, there's just a very few number of  
21 bacteria, and it happens during the operation, during the  
22 joint surgery.

23 PJI can be caused by airborne contamination. We  
24 have also presented evidence about the relevancy of  
25 increased particles and how those are directly correlated

1 with increased bacteria over the sterile field, and an  
2 increase in bacteria in the sterile field increases the  
3 incidence of periprosthetic joint infections.

4 So I'll just go through this very quickly as Your  
5 Honors have certainly heard this. Both the plaintiffs and  
6 the defendants have agreed that bacteria causes  
7 periprosthetic joint infection. They also agree that  
8 inoculation, so the does of bacteria is much smaller when  
9 you're talking about PJI, than something on the skin level,  
10 a surgical site infection.

11 PJI can be caused by airborne contamination.  
12 Dr. Jarvis and Dr. Stonnington put it in their reports, and  
13 we would certainly encourage Your Honors to take a close  
14 look at that time, but also Dr. Wenzel has published and  
15 testified about this, the possibility of airborne bacteria  
16 originating from patient and from the surgical team, that  
17 those suffice to create surgical site infection in these  
18 kinds of procedures, particularly when implants are being  
19 placed, and that has to do with films and vascularity that  
20 we don't need to go into at this point.

21 Dr. Mont agreed periprosthetic joint infection are  
22 caused by airborne contamination, and we get to the study  
23 that was done by Darouiche, and Darouiche really confirms  
24 again, and this is at Exhibit 11, by the way, that for every  
25 ten colony forming units per meter cubed, the increase in

1 infection, there is a probability of an implant infection is  
2 doubled.

3 And the evidence that has been presented to Your  
4 Honors is that the colony forming units that are transported  
5 to the surgical site are well in excess of these additional  
6 ten per cubic meter.

7 So turning again to the international consensus,  
8 everybody agrees that this is a reliable source, but it's  
9 also a source that's a couple years old, and even then, they  
10 were certainly recognizing the fact that bacteria that  
11 arrive at the surgical wound correlate with the probability  
12 of having this kind of infection.

13 And I should say that in the international  
14 consensus, by the way, they say SSI. Well, the entire  
15 consensus was brought together to talk about deep joint  
16 infection. So if you read the full title of the  
17 international consensus, it is International Consensus on  
18 Prevention of Peri Operative Joint Infection, I believe if  
19 I've got that right. So that's what they were focused on.

20 THE COURT: We had a couple comments about the age  
21 of this study. What's the age of the study versus the  
22 filing of the first case in the MDL? The cases were filed  
23 here during the time that this wasn't old.

24 MS. ZIMMERMAN: That is true. That's true, and I  
25 believe that the international consensus came out in 2104.

1 This MDL was assigned in December of 2015. The first cases  
2 that were filed, Walton and Johnson, were in 2013 and 2014,  
3 so right about that time, but I think that the timing with  
4 respect to the international consensus is appropriately Your  
5 Honors' to be aware of, particularly there's been a question  
6 about whether or not the law is really leading science or  
7 following it, and here law is actually following science.

8 These folks at the international consensus were  
9 very concerned about these issues. They recognize the  
10 potential theoretical risk, and they did not have the same  
11 kind of information that we have now, but again, we're  
12 talking about the conclusions that are ultimately reached on  
13 a different data set than what has been presented or what we  
14 know as we stand here in 2017.

15 The methodologies by which we arrive at that  
16 evidence and present it to Your Honors for consideration,  
17 those are well-established methodologies in terms of  
18 particle tracing, computational fluid dynamics, the Bradford  
19 Hill criteria, and so as Ms. Conlin indicated earlier, the  
20 issue here today is not that this is new science.

21 It is that the science that has been developed for  
22 many, many years is being woven together into a package that  
23 makes sense, and it's a package that the international  
24 consensus units has been asking for, and that is really what  
25 the -- and I believe Judge Noel asked some questions about

1 the recognized theoretical risk -- pardon me. It's a been a  
2 late couple of nights -- that the international consensus  
3 recognized the theoretical risk associated with forced air  
4 warming and requested more study be done.

5 Plaintiffs have presented evidence, and the  
6 defendants have agreed as well, with respect to question  
7 number 1 of the international consensu. More bacteria, more  
8 likely you're going to have an infection. Question number  
9 two, Do the bacteria in the operating room correlate  
10 directly with the probability that you're going to have this  
11 infection? Everybody seems to agree, yes.

12 They cite their justification, by the way, and  
13 they say that some studies have suggested that airborne  
14 particulate count should be considered as the potential  
15 surrogate for airborne microbial density. Others have found  
16 correlation between the number of particulates larger than  
17 ten micrometers with a density of viable bacteria at the  
18 site of surgery measured by colony forming units.

19 So it has been suggested that monitoring  
20 particulate count could be used as a real time proxy for  
21 increased risk of wound contamination or infection. This is  
22 not new. This is not developed for litigation inside Your  
23 Honors's courtrooms. This is something that both sides  
24 agree is authoritative. So there's been evidence presented  
25 to Your Honors also with respect to what the defendants have

1 done in the face of various studies and complaints, what  
2 they have done with respect to filtration.

3 And this is an e-mail from Glen Maharaj in 2013  
4 where they are talking about whether or not they can claim  
5 their filters have a HEPA efficiency, and he says we have no  
6 documentation in regards to that for the 750 or the 775.  
7 All we can do is stick by our claim and statement of high  
8 efficiency, which testimony from several witnesses here says  
9 would agree means nothing unless we specify the size of the  
10 thing that's being filtered out and how effective it's being  
11 filtered.

12 So HEPA we know is 99.97 percent efficient  
13 removing those particles down to a .3-micron size, so that's  
14 the import of that kind of efficiency measurement. Just  
15 saying high efficiency doesn't matter on its own without  
16 those other pieces of evidence.

17 So the defendants have failed to warn about  
18 contamination. They've known about it, and we have talked  
19 about it. This is Al van Duren's deposition in March of  
20 this year. He was the 30(b)(6) corporate representative,  
21 and he said, no, 3M is not disputing the Bair Hugger blower  
22 and hose, yep, they can harbor bacteria inside that device,  
23 we're not disputing that.

24 And dating back all the way -- this is an e-mail  
25 from Gary Hansen to Russell Olmsted, and they're talking



1 about the Stocks paper, and they know there's an increase  
2 particle count when the Bair Hugger is being used. So those  
3 are all different pieces of evidence that have been tied  
4 together by the plaintiff's experts in understanding the  
5 risks that Bair Hugger poses to patients across the country.

6 Al van Duren also says, yes, Bair Hugger increases  
7 particles in absolute numbers, and they have no internal  
8 data to refute that. Every study they've done, every study  
9 they're aware of, says that when the Bair Hugger is turned  
10 on, particles go up, and there's been some testimony,  
11 argument from counsel, about whether or not there has been  
12 any reports of infection or other kinds of complains from  
13 customers.

14 And my recollection is that what's been  
15 represented to Your Honors is, there have been no complaints  
16 of that sort of thing, but that's not consistent with some  
17 of the e-mails that we've seen, and I point Your Honors to  
18 this e-mail from Suzanne Tullis to folks at 3M, Mark Scott,  
19 and Suzanne Tullis it says here is the district sales  
20 manager for Arizant in North and South Carolina.

21 And she says, "This issue is everywhere. We have  
22 to develop a better strategy besides the Zink article," and  
23 this is in response to an e-mail she received from Vicki  
24 Jones. The subject is "Forced Air Warming Devices," and at  
25 the bottom you can see it says, "Dr. Bratzer, several of our

1 orthopedic physicians are refusing the use of forced air  
2 warming devices for joint replacement procedures at our  
3 facility. Their position is that they contribute to post op  
4 wound infections because of the circulating air, air  
5 turbulence, et cetera. The literature they have and what I  
6 found seems to support their position."

7 So they're getting questions from the field. Did  
8 they do any studies to refute this? If they had, I think  
9 that those would have been presented to Your Honors. They  
10 were getting concerns about contamination from people in the  
11 field.

12 Here's an e-mail where Al Van Duren again is  
13 recommending that when there is a known device -- if you  
14 look at the bottom here, it says we have a model 750 unit,  
15 serial number provided, and it has cultured positive for  
16 Acinetobacter. That is a bacteria, and Al Van Duren says,  
17 "Do not scrap the unit, remove and discard the filter in the  
18 biohazardous waste container."

19 So it's simply, it is not consistent with the  
20 evidence to say that there have not been reports from the  
21 field of contaminated devices, and we have only some of the  
22 evidence here, but in the face of that, when Al Van Duren  
23 was asked at his deposition as a corporate representative,  
24 well, what have you done with respect to safety validation?  
25 What did you do with the filter? And his answer was, "I

1 don't believe that any particulate filtration efficiency  
2 studies were completed," and that was with the 505.

3 And we said, well, have you done any biological  
4 testing of the filter? He says on behalf of the company,  
5 I'm unaware, "the company is unaware of any biological  
6 testing conducted during the design of the 505."

7 Michelle Hulse-Stevens was asked some questions  
8 about why that wasn't studies, and when Mr. Ciresi was  
9 deposing her he asked, "Are there other types of studies  
10 that you believe provide adequate evidence for the adoption  
11 of particular interventions, which could be less difficult  
12 to conduct?"

13 And we're getting at the aerobiology study several  
14 of their consultants have been recommending that they do,  
15 and she says yes. And well, that particular study, that has  
16 been recommended, that hasn't been conducted, correct?

17 "We have not conducted that study."

18 Mr. Ciresi asked, "And decisions have been made at  
19 the highest levels not to conduct that studies, correct?"

20 The answer, "Yes." And Michelle Hulse-Stevens'  
21 deposition is an exhibit along with the e-mails that support  
22 that decision.

23 In fact, the other thing that the company did was  
24 they discouraged independent studies, and here is an e-mail  
25 from Gary Hansen, again internally, saying here's our

1 strategy. "Our first step with ECRI should be to prevent  
2 them from doing their own testing, rather, rely on the  
3 published data."

4 And at the bottom you can see where it's  
5 highlighted, "I'd like to convince them that the valid  
6 testing is an arduous undertaking."

7 So the increase in bacteria in the sterile field  
8 also increases the incidence of these kinds of infection.  
9 Dr. Jarvis talks about that. Dr. Wenzel agrees.  
10 Dr. Wenzel, incidentally, may be interested to hear the  
11 argument that was presented before Your Honors yesterday  
12 that apparently Stocks and Darouiche are also either  
13 engaging in some sort of academic fraud or cooking their  
14 studies because they're hocking some sort of other warming  
15 device on the side.

16 And I think that that had to do with a new device  
17 that was studied in the Darouiche studies, and Mr. Goss --  
18 and I'm happy to find a copy of the particular cite to the  
19 transcript -- said, well, you know, the only other people  
20 that looked at this may be the reason that they came up with  
21 the results that they did was because they also had a  
22 product to sell.

23 Really at the end of the day, all of that goes to  
24 the weight, not to the admissibility, but Dr. Wenzel at any  
25 rate agreed at his deposition that Darouiche, he's an

1 expert, and Dr. Darouiche, of course, found correlation  
2 between increased bacteria in the sterile field and risk of  
3 infection.

4 All right. And so now I turn your attention, and  
5 this is the document that I think Mr. Hulse was really  
6 forecasting for Your Honors. What else did this company  
7 know? When did they know it? And this is Exhibit 2 to our  
8 motion papers, and what this is is a study protocol dated  
9 June 23rd of 2007, and it's a study protocol for the Bear  
10 Paws device.

11 Bear Paws is another device that is used to warm  
12 patients to maintain normothermia, and what Al Van Duren  
13 says in September of 2007 is that if you pre-warm a patient  
14 before the surgical incision happens, you are capable of  
15 preventing significant surgical hypothermia for three hours.  
16 That means that you don't need to use forced air warming at  
17 all if you get the patient warm enough.

18 That's Al Van Duren says in his document here, but  
19 the other thing that he says, and we highlighted this in our  
20 brief, and this is at Table 1. He says, and this is, it's a  
21 table that lists advantages and disadvantages of using the  
22 Bear Paws prewarming versus the Bair Hugger during an  
23 operation.

24 Advantages: Inexpensive. Bear Paws is safe.  
25 Bear Paws can be used when intraoperative warming is

1       contra-indicated (aortic cross clamp, orthopedic cases.) It  
2       also, one benefit, it does not contaminate the sterile field  
3       to use the Bear Paws before a surgery starts.

4               Go down two lines on the same chart. Again Al Van  
5       Duren. This is not Dr. Augustine. Dr. Augustine is not in  
6       the picture. Bear Paws reduces the incidence of surgical  
7       site infection, and it reduces the potential for nosocomial  
8       transmission of pathogens by eliminating the need for  
9       intraoperative warming.

10              So their own corporate documents say that the Bair  
11       Hugger may not be well indicated in orthopedic surgeries,  
12       but they didn't tell the orthopedic surgeons about that, and  
13       Mr. Van Duren in his corporate deposition, he admitted to  
14       that fact as well.

15              So they say that pre warming with their own forced  
16       air warming product is equally effective at keeping the  
17       patient warm for at least three hours, which is the length  
18       of time certainly within which the vast majority of the  
19       cases before Your Honors were completed within three hours,  
20       and it eliminates these known risks. It eliminates the  
21       risks, and they were known at least in 2007.

22              The other piece of evidence that I would point  
23       Your Honors to is this particular document, and that is at  
24       Exhibit 2, and the thing that really matters here, this is  
25       an internal document, and the notation on the side is not

1 mine. That is from AVD1, and the testimony presented in  
2 this litigation is that that's Al Van Duren.

3 And he's commenting on this protocol on this  
4 particular section, and it says, the paper itself says there  
5 is no evidence that forced air warming increases risk of  
6 surgical site infections and considerable evidence that it  
7 does not, most recently from the U. S. National Institutes  
8 of Health. Numerous studies have shown it does not  
9 contribute to bacterial contamination in operating theaters.

10 So this is going to be a talking point for sales,  
11 by the way, and Al van Duren sees this, and he puts a  
12 comment on, and what does it say? It says actually there is  
13 evidence that forced air warming use increases the risk.  
14 This evidence was the motivation for Dr. Memarzadeh's work.  
15 This isn't Augustine. This is Al van Duren. This is the  
16 gentleman that they put up as their corporate representative  
17 when they did a 30(b)(6) deposition in March of this year,  
18 and this is back in 2010.

19 Now Judge Noel, before we left yesterday, you  
20 asked, you forecasted that you were going to ask about the  
21 nine studies, and I won't belabor this because I know it's  
22 getting to be long, but what I will say is that Your Honor  
23 appropriately recognized the fish analogy and the pond.

24 What I would say is that I think that Judge Noel's  
25 questions to Mr. Gordon were particularly helpful because 3M

1 does point to these nine studies, and they say that means  
2 that the Bair Hugger is safe. Now, first of all this  
3 morning, Mr. Gordon conceded that that was attorney argument  
4 and interpretation of those studies.

5 And really that means that this goes to the  
6 weight, not to admissibility, but to get back to the  
7 question that Judge Noel asked, the converse is also true.  
8 If 3M had any other studies besides these nine that would  
9 speak to the safety of this particular device, we can be  
10 sure that we would have seen it by now, but these are the  
11 nine that they've got.

12 And we can walk through each one of the nine. The  
13 first one is Hall. This is not a published peer reviewed  
14 paper. This is a poster presentation. There are 20  
15 patients, 10 are Bair Hugger, 10 are non Bair Hugger. It's  
16 a completely different kind of surgery, it's an oral  
17 surgery, not ultra clean.

18 And there are six collection sites, but four were  
19 at each corner of the room, two were at the operating room  
20 table, one was the surgical site. So the Hall paper does  
21 not speak to whether or not there would be bacteria at the  
22 surgical site.

23 Similarly with respect to Zink, again this was a  
24 different device. It was at a lower temperature and a lower  
25 air flow rate. There's only eight patients here, and they



1 use a completely different blanket. It was the lower body  
2 blanket. The blankets at issue in I would say 99 percent of  
3 the cases before Your Honors are the upper body 522 blanket.

4 This was not a real surgery. These were  
5 volunteers that were laying down on the table, and I don't  
6 know if they got the pizza and the beer, but that's what was  
7 happening here. The Dirkes study, the Bair Hugger was set  
8 to ambient temperature setting. It wasn't set to warm, and  
9 we think that that is relevant for all the reasons that we  
10 have presented with respect to the CFD yesterday.

11 Avidan, again they're measuring bacteria at  
12 various points inside the machine. Tumia as well, and we'll  
13 walk through each of these, but suffice it to say that as  
14 Mr. Gordon indicated, there's different interpretations for  
15 each one of these studies that plaintiff's experts are  
16 certainly prepared to provide their interpretation of that,  
17 and the interpretation of all of those should go to the  
18 weight, not the admissibility.

19 MAGISTRATE JUDGE NOEL: All nine of these studies,  
20 though, is Mr. Gordon is correct that they are measuring  
21 bacteria? They're not looking for infection. Is that a  
22 correct statement?

23 MS. ZIMMERMAN: That is correct Your Honor.

24 THE COURT: And they're looking for bacteria on  
25 these agar plates?

1 MS. ZIMMERMAN: That is my understanding, yes,  
2 Your Honor.

3 MAGISTRATE JUDGE NOEL: Thank you.

4 MS. ZIMMERMAN: If the Court has no more  
5 questions -- I don't know if Mr. Ciresi was -- if the Court  
6 has no more questions, we're all done.

7 THE COURT: All right. Thank you.

8 JUDGE LEARY: Thank you.

9 THE COURT: Any rebuttal?

10 JUDGE LEARY: You know, I do have one question for  
11 you, Ms. Zimmerman, and I apologize for the delay in asking  
12 it.

13 MS. ZIMMERMAN: No problem.

14 JUDGE LEARY: With regard to the Frye Mack  
15 standard for the Minnesota state cases, am I correct in  
16 understanding that you're relying on the Texas case as the  
17 basis for saying that Frye Mack was satisfied in that the  
18 methodology is generally accepted within the relevant  
19 scientific community?

20 MS. ZIMMERMAN: I should clarify. So the Texas  
21 case is a federal case, and so it's applying *Daubert*. We  
22 think that it's helpful in understanding what weight should  
23 be given to these kinds of studies, but in Minnesota as long  
24 as, under Frye Mack and *Gold versus Tharaldson*, as long as  
25 the methodologies that the experts employ, and that is

1 literature gathering, Bradford Hill criteria, the  
2 computational fluid dynamics.

3 As long as they're qualified to do it, and there's  
4 been no challenge to the qualifications of any of these  
5 experts, and as long as they did it correctly, anything else  
6 can be sussed out during cross-examination in front of the  
7 trier of fact.

8 THE COURT: That's what I understood you to have  
9 said before. Thank you.

10 MS. ZIMMERMAN: Thank you, Your Honor.

11 MR. HULSE: Good morning -- good afternoon again.  
12 Good afternoon Judge Noel.

13 I just want to cover some factual points, but  
14 first, of course, the Minnesota Rule of Evidence 702 applies  
15 the requirement of general acceptance to novel theories.  
16 That's the terminology in Minnesota Rule 702. I think it's  
17 beyond dispute that what we have here is a novel theory, and  
18 so the general acceptance rule applies.

19 *Gold versus Tharaldson* is governing, and even if  
20 Judge Leary is inclined to look at the Texas federal case, I  
21 think what you'll find in that case, too, is that the  
22 defendant in that case didn't actually challenge the  
23 validity of the studies that the plaintiff's experts relied  
24 on. It stated that specifically in the decision.

25 First point, Ms. Conlin said that we have no idea

1 if the data that Dr. Holford looked at came from Dr. Reed.

2 And Brett, can you bring that up?

3 All right. So this is the Excel spreadsheet that  
4 was produced by Augustine. This was reviewed by  
5 Dr. Holford, and what the meta data is, that showed who last  
6 modified it when they last modified it, it's Dr. Mike Reed.  
7 This was the data that was sent to Augustine. That doesn't  
8 match the final data that is reported in the published  
9 study. You can take that down.

10 Ms. Conlin also said, brought up a quote from  
11 Dr. Holford, purporting to admit that there is no literature  
12 that supports either antibiotics or anti thrombo prophylaxis  
13 as confounders. As we've explained before, Dr. Holford is a  
14 statistician. He partnered with Dr. Borak, professor of  
15 epidemiology, and Dr. Wenzel and Dr. Mont, who reviewed the  
16 literature and gave the opinions based on the literature,  
17 scientific literature, that in fact both are well supported  
18 as confounders, and that wasn't consider Dr. Holford's job.  
19 He was the biostatistician.

20 It was also asserted that the Brimmo study which  
21 concludes that rivaroxaban, the anti thrombosis regimen,  
22 that was in place when you saw the spike in infections  
23 purchasing during the Bair Hugger period in the McGovern  
24 study, the claim was that Brimmo is nowhere in the case.  
25 This is just something that the lawyers came in with, the

1 Brimmo study.

2 Dr. Wenzel relied on the Brimmo study at pages  
3 255, 258, 259, 2602 of his deposition, and Dr. Mont  
4 specifically cites it in his report where he concludes that  
5 it's a confounder. There was a discussion of Dr. Sessler's  
6 studies and the increase in particulates that was found in  
7 the Sessler studies. It's all submicron particles.

8 It was claimed that Dr. Kurz, the author of the  
9 study, and this was claimed before, and I thought we had  
10 already dealt with this, has disavowed that there is any  
11 benefit to patient warming. So I'm going to quote again  
12 Dr. Kurz's actual testimony. This is page 200 of her  
13 deposition.

14 Question: I want to make it clear, you're not  
15 saying, or are you saying, that the evidence today no longer  
16 supports the idea that maintenance of normothermia reduces  
17 the risk of surgical site infections?

18 Answer: I think, if I understand you correctly,  
19 I'm not saying that. I'm saying that I still believe that  
20 maintenance of normothermia decreases infection risk, but  
21 the effect size might be closer to 30 percent reductions or  
22 so, which is in effect a humongous, enormously large effect  
23 size for any medical intervention. That's what Dr. Kurz  
24 testified.

25 Finally, one of the documents that Ms. Zimmerman

1 put up talked about the effectiveness of the filter in the  
2 Bair Hugger, and as we've presented in the evidence, and  
3 it's there in our expert reports, too. The Bair Hugger  
4 filter is MERV14. That is the ASHRAE standard for operating  
5 rooms, and in fact, when the Cleveland Clinic conducted its  
6 study where it compared infection rates between the Bair  
7 Hugger with its MERV14 filter and the Stryker with its HEPA  
8 filter, there was no statistically significant difference in  
9 infection, and that was an extremely large trial.

10 And I would just like to end on the Cleveland  
11 Clinic study. It is in the record, and I urge the Court to  
12 look at it. In the Bair Hugger period, Cleveland Clinic had  
13 an infection rate of .47 percent, and if the plaintiff's  
14 theories, their possibilities, their potential theoretical  
15 risk that they've advanced here today were true, if it  
16 played out in the real world, how could the Cleveland Clinic  
17 using the Bair Hugger possibly have achieved a 0.47 percent  
18 infection rate?

19 This underscores where you had the higher  
20 infection rate found in the McGovern study the critical  
21 importance of the confounders of the antibiotics, of the  
22 antithrombotics, of fitness for surgery, of obesity, of all  
23 the other well-established and recognized factors in  
24 infection rates.

25 And finally, just to come back to *Joiner*, and

1     *Joiner* again was a decision where the Supreme Court affirmed  
2     the exclusion of causation experts who relied on  
3     epidemiological studies. There comes a point where the  
4     inferences of causation that are drawn from scientific  
5     literature are too far.

6             The gigantic leap, the flying leap that the  
7     plaintiffs medical experts have taken here, they point to no  
8     example. Plaintiff's counsel point to no example where they  
9     have ever reached these kind of causation conclusions based  
10    on this material, nowhere in their professional lives. This  
11    is courtroom science. It's not real science.

12            We ask the Court again to exclude the plaintiff's  
13    medical experts and grant summary judgment. Thank you.

14            THE COURT: Thank you.

15            Were there any documents that were discussed here  
16    put up that are under seal that we can unseal? Do we have  
17    any sealing issues?

18            MR. HULSE: Our favorite topic.

19            MS. ZIMMERMAN: Of course the Courts will not be  
20    surprised that plaintiffs believe that all of this evidence  
21    should be publicly available.

22            MR. HULSE: Well, we may disagree on some points,  
23    but I also know from experience with Your Honors that when  
24    it comes to summary judgment, it's a pretty restrictive what  
25    remains under seal. So we would like to follow the process.

1 We have got a lot to go through, but of course the  
2 defendants will keep that in mind, the public's right to  
3 know.

4 THE COURT: Okay. I just wonder whether there  
5 were sealed documents that were discussed here in open  
6 court, and if there were, then those presumably could be  
7 unsealed, but you'll go through those.

8 MR. HULSE: Right. And I think it would almost  
9 exclusively be things that were discussed, sort of the  
10 internal corporate documents, but maybe upon, you know, a  
11 little bit of thought, we can get past the sealing issue on  
12 those.

13 THE COURT: Okay. Just something to consider.

14 MAGISTRATE JUDGE NOEL: Are we done? I just want  
15 to say I'm very impressed with all of the lawyers in this  
16 case. In the three days we've gone through 17 motions, 51  
17 memos. I'm amazed at your, both sides' command of all of  
18 the documents, and thank you for, on a very interesting  
19 presentation.

20 I've enjoyed being here.

21 THE COURT: Thank you.

22 MS. ZIMMERMAN: Thank you.

23 THE COURT: We don't take enough breaks. I just  
24 want to remind you that the head of China just gave a  
25 three-hour speech with no break at all.



1 JUDGE LEARY: I am sorry. If I could, on the  
2 punitive damages motion, I'm requesting submissions by both  
3 parties with regard to their view of the evidence and the  
4 law and in the form of proposed findings, as well as the  
5 judgment. If there is any recitation -- let me back up.

6 I rely heavily on representations based on  
7 evidence that exists in the record. That's what my  
8 expectation is. If there's any reference to the evidence, I  
9 want to see direct quotes to the literature or to the  
10 depositions, whatever is being quoted. You can put it in  
11 the body of the document, or you can put it in an annotation  
12 in the footnote.

13 But I want it to be as complete and exhaustive as  
14 it was with regard to the punitive damages. I'll give you  
15 three weeks to submit that or three weeks from today's date.

16 MS. ZIMMERMAN: Thank you, Your Honor.

17 MR. HULSE: Thank you, Your Honor.

18 THE COURT: And then, Mr. Blackwell, it looks like  
19 you're anticipating my next question, which is -- and --  
20 Ms. Zimmerman, same thing for you -- we will take the hard  
21 copies of the presentations, and Ms. Zimmerman, do you have  
22 the slides that you used today in your argument and,  
23 Ms. Conlin, as well?

24 Not right this second, but can you get it?

25 MS. ZIMMERMAN: If we don't have them, we will

1 make sure to have them messengered over to you. We also  
2 were prepared to provide a digital copy of Dr. Elgobashi's  
3 video for the Courts, as that was played in the power points  
4 yesterday, and I don't know that it would work on hard copy.

5 THE COURT: Did we have a video?

6 MR. BLACKWELL: There was a little clip yesterday.

7 THE COURT: Oh, yeah, that little clip.

8 MAGISTRATE JUDGE NOEL: Red and green and yellow.

9 MR. BLACKWELL: Kind of looked like Dante's  
10 Inferno.

11 THE COURT: Well, you would know.

12 MR. BLACKWELL: Yes.

13 THE COURT: So you're just talking that. You're  
14 not going to give us a whole --

15 MS. ZIMMERMAN: No, I don't think we could get it  
16 on a flash drive. There is a lot of data.

17 THE COURT: That's wonderful. Really, it was such  
18 a pleasure to talk to you folks, and we'll look forward to  
19 any submissions and take the matters, many, many matters,  
20 we'll take them all under advisement and issue an order in  
21 due course.

22 JUDGE LEARY: I will accept the Elgobashi  
23 demonstration, too, and thank you, and I'll accept your dec  
24 copies, as well as plaintiff's dec copies as well. Not now.

25 MS. ZIMMERMAN: I will see if we have got them,

1 otherwise I will make sure you get them.

2 THE COURT: Do we have a status conference that we  
3 should talk about whether it makes sense? This is October.  
4 I'm sorry. I yawned a couple times today. These were long  
5 days for all of us. I realize they were way, way longer for  
6 you than us.

7 MR. BLACKWELL: November 16th I'm hearing.

8 THE COURT: I don't think that makes sense.

9 MR. BLACKWELL: Yeah. We agree that it doesn't  
10 make sense to have it November 16th. This is sort of what's  
11 happening.

12 MAGISTRATE JUDGE NOEL: This is your report.

13 MS. ZIMMERMAN: I think that's right. Given the  
14 new scheduling order, we are all going to be very busy, I'm  
15 sure, on bellwether issues as well, working on depositions  
16 and that sort of thing.

17 THE COURT: Okay.

18 MR. BLACKWELL: I do want to say, and I think I  
19 speak for just about all the lawyers. This is about as big  
20 a case as any of us can be involved in, and it's kind of  
21 rare to be in joint session of both courts, and we've never  
22 been in front of a more accessible court than we've  
23 experienced in this case.

24 And it's really helped things to go much more  
25 smoothly, and I think we have all appreciated it.

1 JUDGE LEARY: I also want to echo the comments of  
2 my colleagues. The professionalism you've all demonstrated  
3 throughout this process has been really a credit to the  
4 profession. It's been an honor to preside over this, and  
5 also give your colleague best wishes. I hope he's feeling  
6 better as well, Mr. Gordon.

7 MS. ZIMMERMAN: I will check in with him after the  
8 hearing. Thank you. I will do that.

9 THE COURT: Yeah. Not my dream, but these two  
10 always wanted to be on a three-judge panel.

11 JUDGE LEARY: I no longer dream it.

12 THE COURT: Thank you. We're in recess.

13 (Court adjourned at 1:26 p.m.)

14  
15 \* \* \*

16  
17 I, Maria V. Weinbeck, certify that the foregoing is  
18 a correct transcript from the record of proceedings in the  
19 above-entitled matter.

20  
21 Certified by: s/ Maria V. Weinbeck

22 Maria V. Weinbeck, RMR-FCRR  
23  
24  
25